2. Case Studies from the Committee's Investigation

In addition to designing an effective system to monitor suspicious orders, many of which include the use of thresholds, distributors must also ensure the systems are enforced properly. In this investigation, however, the Committee found many instances in which distributors allowed West Virginia pharmacies that received a high volume of opioids to exceed or dramatically increase their drug thresholds. It appears that distributors either failed to enforce thresholds or approved pharmacies' requests to increase their thresholds without properly vetting the reasons why increases were sought. This section will expand on four case studies exemplifying the need to set, vet, and enforce thresholds:

- H.D. Smith's lack of thresholds, which allowed Tug Valley Pharmacy's hydrocodone orders to surge unchecked;
- Cardinal's thresholds for Hurley Drug Company, which were set far above the average distribution to the pharmacy;
- Cardinal's thresholds for Family Discount Pharmacy, which were increased without adequate vetting or investigation; and
- McKesson's thresholds for Sav-Rite Pharmacy No. 1, where the average sales of the pharmacy surpassed the monthly threshold on a daily basis, yet McKesson continued to distribute controlled substances.

a. Case Study on H.D. Smith: The Importance of Establishing Thresholds

The failure to establish a threshold limit for controlled substances leaves distributors at risk of violating the CSA; without thresholds, it is much more difficult for distributors to identify and report suspicious orders. As recently as 2015, more than one-third of distributors were estimated to not utilize a threshold system.[735] Through its investigation, the Committee learned that H.D. Smith did not utilize a threshold system prior to 2008.[736] The company's failure to set thresholds or unit reporting limits (URLs) prior to 2008 allowed controlled substance purchases for one pharmacy examined by the Committee to increase rapidly in less than a year.

Between 2007 and 2009, H.D. Smith distributed more than 2.23 million dosage units of hydrocodone to Tug Valley Pharmacy, located in Williamson, West Virginia, population

[735] U.S. Gov't Accountability Office, Prescription Drugs: More DEA Information about Registrants Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access, GAO-15-471 at 27 (June 25, 2015), *available at* https://www.gao.gov/assets/680/671032.pdf.
[736] Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

two doctors it previously flagged as problematic prescribers, Drs. Diane Shafer and Katherine Hoover.[757]

The Committee's findings regarding H.D. Smith's distribution to Tug Valley demonstrate the failures that can occur when thresholds are not utilized. H.D. Smith brought Tug Valley on as a customer before its CSOMP and threshold limits were established. Without threshold limits in place, the pharmacy increased its hydrocodone purchases by more than 1,000 percent over a five-month period. Moreover, even after increasing its due diligence of the pharmacy, but before implementing a threshold system, H.D. Smith continued to supply Tug Valley with a higher number of opioids than its later-implemented thresholds would have allowed.

b. *Case Study on Cardinal Health: Accurately Setting Thresholds*

For those distributors that utilize thresholds, it is critical that the thresholds be accurately set. When distributors set thresholds far above the levels at which pharmacies purchase controlled substances, the threshold systems cannot be effective at detecting possible suspicious orders.

Hurley Drug Company ("Hurley"), located in the approximately 3,191-person town of Williamson, West Virginia,[758] received more than 10.58 million doses of hydrocodone and oxycodone from wholesale distributors between 2006 and 2016.[759] Cardinal Health distributed more than one-third of the supply. From 2006 to 2014, Cardinal distributed 3.71 million doses of hydrocodone to Hurley.[760]

Cardinal's Distribution to Hurley Drug Company[761]	
2006	
Drug	**Dosage Units**
Hydrocodone	739,800
Oxycodone	67,200
2007	
Hydrocodone	11,400
Oxycodone	3,600
2008	
Hydrocodone	585,700
Oxycodone	0
2009	
Hydrocodone	635,000
Oxycodone	0
2010	

[757] Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).
[758] U.S. Census Bureau, American FactFinder, *Williamson city, West Virginia,* https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml.
[759] U.S. Drug Enforcement Admin., ARCOS data (On file with Committee).
[760] *Id.*
[761] *Id.*

Hydrocodone	130,830
Oxycodone	0
2011	
Hydrocodone	496,060
Oxycodone	41,100
2012	
Hydrocodone	521,180
Oxycodone	55,100
2013	
Hydrocodone	426,740
Oxycodone	57,100
2014	
Hydrocodone	167,000
Oxycodone	35,720
Total	**3,973,530**

FINDING: Between 2006 and 2014, Cardinal distributed 3.71 million doses of hydrocodone to Hurley Drug Company, located in Williamson, West Virginia.

Between June 2008 and March 2011, Cardinal set Hurley's monthly hydrocodone threshold at 155,000 dosage units, allowing the pharmacy to purchase up to that amount of hydrocodone each month without triggering a threshold event and related investigation.[762] In 2009, Cardinal distributed 635,000 doses to Hurley—an average of 52,916 doses a month.[763] In 2010, it distributed 130,830 doses of hydrocodone to Hurley—an average of 10,902 doses a month.[764] The threshold Cardinal set for Hurley would have allowed the pharmacy to purchase nearly three times more hydrocodone a month than it actually received in 2009 and 14 times more than it received in 2010 without triggering a threshold review. While the Committee has not opined on the appropriate threshold level, the fact that Hurley's hydrocodone threshold remained the same despite the wide variance in the pharmacy's actual dispensing levels indicates to the Committee that the pharmacy's actual hydrocodone dispensing was not a factor considered by Cardinal.

FINDING: From June 2008 to March 2011, Cardinal set Hurley Drug Company's hydrocodone threshold at 155,000, three times higher than its average monthly purchases in 2009 and 14 times higher than its average monthly purchases in 2010.

The earliest reference to a threshold limit found in documents Cardinal provided the Committee indicates that Hurley's hydrocodone threshold was set at 10,000 dosage units a

[762] Cardinal Health Inc., Threshold change history for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).
[763] U.S. Drug Enforcement Admin., ARCOS data (On file with Committee).
[764] *Id.*

month in January 2008.[765] The 10,000-dosage threshold remained in place through June of 2008 when Cardinal increased Hurley's threshold. Between June 9 and June 23, 2008, Cardinal increased the hydrocodone threshold for Hurley on five separate occasions, culminating in a threshold of 155,000 dosages of hydrocodone a month.[766] This was a fifteen-fold increase in just two weeks. Moreover, the resulting 155,000-dosage per month threshold remained in place for nearly three years.

Hydrocodone Threshold Adjustments for Hurley Drug Company[767]		
Date of Change	**Initial Monthly Dosage Threshold**	**New Monthly Dosage Threshold**
June 9, 2008	10,000	27,000
June 13, 2008	27,000	37,500
June 17, 2008	37,500	45,000
June 19, 2008	45,000	54,000
June 23, 2008	54,000	155,000
March 8, 2011	155,000	66,501
December 12, 2012	66,501	55,005
November 7, 2013	55,005	42,005
February 13, 2015[768]	42,005	7,000

FINDING: Between June 9 and June 23, 2008, Cardinal increased the hydrocodone threshold for Hurley Drug Company on five separate occasions, culminating in a threshold of 155,000 dosages of hydrocodone a month. This was a fifteen-fold increase in the threshold in two weeks.

[765] The 10,000-dosage threshold is referenced in a report prepared ahead of a June 2008 site visit to the pharmacy. Cardinal Health, QRA Site Visit Preparation for June 3, 2008 visit to Hurley Drug Company, undated (On file with Committee).

[766] Cardinal Health Inc., Threshold change history for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).

[767] *Id.*

[768] Cardinal Health stopped distributing oxycodone and hydrocodone to Hurley Drug Company in 2014, and DEA ARCOS data also shows that no hydrocodone or oxycodone were distributed to the pharmacy in 2015 or 2016. Cardinal told the Committee that it lowered Hurley's thresholds after it stopped distributing those drugs to reflect that Hurley was no longer able to order those products. *See* Letter from Counsel to Cardinal Health, to Staff, H. Comm. on Energy and Commerce (Sept. 13, 2018) (On file with Committee).

i. Cardinal's Documentation of Threshold Increases for Hurley Drug Company

Cardinal did not formalize its standard operating procedures (SOP) until December 2008, after the five hydrocodone threshold increases for Hurley in June 2008. Before the SOPs took effect, thresholds were monitored by distribution center employees who "were instructed to identify any orders that appeared excessive in relation to what other customers were buying and/or the customer's purchase history."[769] As described previously, Cardinal also used an algorithm designed by the DEA[770] to identify order amounts that should be reported to the DEA through a monthly ingredient limit report.

Other than a chart listing Hurley's hydrocodone threshold increases, Cardinal provided no documentation on the pharmacy's 2008 threshold increases. Cardinal's due diligence and threshold documentation for Hurley provides no explanation as to why any of the five hydrocodone threshold increases were made in June 2008. Cardinal also appeared not to produce any hydrocodone threshold event reports during the approximately three years from June 2008 to March 2011 when Hurley's threshold was set at 155,000 dosage units—an indication that Hurley never hit its hydrocodone threshold during that time.[771] Had Hurley hit its hydrocodone threshold, policies implemented by Cardinal in December 2008 state that the pharmacy would have been required to provide documentation validating the order, and that the Quality and Regulatory Affairs team would review the documentation and the pharmacy's threshold would be evaluated.[772] Moreover, based on documentation provided to the Committee, Cardinal did not independently reevaluate the threshold between June 2008 and March 2011, including by comparing the threshold level to the amount actually distributed by Cardinal, to determine whether it was accurately set.

FINDING:	**Cardinal's due diligence and threshold documentation for Hurley Drug Company provides no explanation as to why any of the five hydrocodone threshold increases were made in June 2008.**

FINDING:	**Based on documentation provided to the Committee, Hurley Drug Company did not hit its hydrocodone threshold in the approximately three years it was set at 155,000 dosage units a month.**

[769] Letter from Counsel to Cardinal Health Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Apr. 25, 2018 (On file with Committee).
[770] *See* U.S. Drug Enforcement Admin., *Report to the U.S. Attorney General*, Oct. 1998 (On file with Committee); *see also* Letter from Counsel to Cardinal Health, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Apr. 25, 2018 (On file with Committee).
[771] Cardinal was unable to confirm whether any threshold events occurred between June 23, 2008, and March 8, 2011, when the hydrocodone threshold was set at 155,000 dosage units. *See* Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).
[772] Cardinal Health Inc., Standard Operating Procedures, Sales – threshold event (Dec. 22, 2008) (On file with Committee).

As the documentation provided by Cardinal did not include any direct explanation for the threshold increases, the Committee examined other documents provided by Cardinal for insight into the threshold increases. Not only does the documentation fail to provide an explanation for the rapid increase in the thresholds, but the documents show that Cardinal learned of derogatory information regarding the pharmacy and failed to reevaluate the thresholds.

Included in Cardinal's due diligence files for Hurley Drug Company was documentation for two site visits conducted at the pharmacy between 2008 and August 2012. One site visit took place on June 3, 2008, just before the pharmacy's hydrocodone thresholds were dramatically increased, and another on June 10, 2009, after the 155,000-dosage unit threshold was in place.[773]

A "QRA Site Visit Preparation" document, seemingly prepared before the June 3, 2008, site visit states that Hurley hit its 10,000-dosage unit threshold for hydrocodone in January 2008 but makes no other reference to the pharmacy's thresholds.[774] The "Data Collection Worksheet-QRA Visit" that follows within the same document and appears to document information collected during the site visit additionally indicates that, among other things, Cardinal was then a secondary supplier to the pharmacy, 28 percent of Hurley's prescription sales were controlled substances, and the pharmacy was projected to see an increase in hydrocodone sales.[775] Both parts of the document—the "QRA Site Visit Preparation" and the "Data Collection Worksheet-QRA Visit"—state that Hurley filled prescriptions for Dr. Katherine Hoover's pain management clinic.[776] The "Data Collection Worksheet-QRA visit" is reproduced in part below:

[773] Cardinal Health Inc., Memorandum on Hurley Drug Company (June 3, 2008) (On file with Committee); Cardinal Health, Inc., Memorandum on Hurley Drug Company (June 16, 2009) (On file with Committee).
[774] Cardinal Health Inc., QRA Site Visit Preparation for June 3, 2008 visit to Hurley Drug Company, undated (On file with Committee).
[775] Cardinal Health Inc., Data Collection Worksheet – QRA Visit, Hurley Drug Company, undated (On file with Committee).
[776] *See* Cardinal Health Inc., QRA Site Visit Preparation for June 3, 2008 visit to Hurley Drug Company, undated (On file with Committee); *see also* Cardinal Health, Inc., Data Collection Worksheet – QRA Visit, Hurley Drug Company, undated (On file with Committee).

14. Other Pharmaceutical Distributors (Noted Changes in Last year): HD Smith, Cardinal Health, Harvard, Masters, Top Rx. Currently HD Smith primary, Cardinal secondary

15. % of Prescription Sales = Controlled: 28%

16. New Physicians in Area: No

17. Proximity/Number of Pain Clinics/Weight Loss/Cancer Clinic:
Pain management clinic in walking distance (2 doors) from above listed pharmacy.

18. Practitioners Involved in Pain Management/Weight Loss or Oncology in the Area:
Mountain Medical, Dr. Hoover (DEA# [redacted]) [redacted] and [redacted] are also located in the immediate area (2 doors down from pharmacy)

19. Any Suspicious Prescribing of Controlled meds by Area Practitioners:
No

20. Location of Controlled Medications in Pharmacy:
Alphabetical on shelves, mixed with non-controlled

21. Controlled Medications Most Prescribed:
Hydrocodone

22. Projected Increase of Controlled Sales/by Name:
Hydrocodone

A one-page memorandum completed after the site visit concluded that "the pharmacy does not represent a significant risk for diversion."[777] As discussed above, in the three weeks following the site visit to Hurley, Cardinal increased the pharmacy's thresholds on five occasions, increasing it from 10,000 doses a month to 155,000 doses a month.

Just three months later, in September 2008, Cardinal learned of derogatory information about Dr. Hoover, specifically that two nearby Kentucky pharmacies would not fill prescriptions

[777] Cardinal Health Inc., Memorandum on Hurley Drug Company (June 3, 2008) (On file with Committee).

from her based on concerns about her practice.[778] A memorandum included in the customer files for both Hurley Drug Company and Family Discount Pharmacy stated:

> [Pharmacist] stated that he has ridden by the office of Dr. Hoover and there are lines of people standing outside, waiting to get in the office. He stated that he was not comfortable accepting prescriptions from her and has turned customers away.[779]

Cardinal investigators subsequently verified that Dr. Hoover's license was valid in West Virginia and researched her practice, finding three prior disciplinary actions, and documented the findings in the same memorandum.[780] Despite learning of this derogatory information, Cardinal did not make any adjustments to Hurley's threshold or undertake an evaluation of the thresholds at this time.

FINDING:	**Cardinal did not reevaluate the threshold between June 2008 and March 2011 to determine whether it was accurately set. This includes after learning of derogatory information regarding Dr. Katherine Hoover, a doctor for whom Hurley Drug Company filled prescriptions.**

Cardinal conducted a second site visit at Hurley in June 2009 and a pharmacy questionnaire was completed within two weeks of the visit.[781] Neither the memorandum documenting the June 10, 2009, site visit nor the questionnaire make mention of Hurley's drug thresholds or indicate that any thresholds were reevaluated in connection with the site visit.

The memorandum indicates Cardinal requested a drug utilization report, which it received and forwarded to Cardinal's QRA-Anti-Diversion division.[782] Presumably, Cardinal could have discerned from the drug utilization report that the hydrocodone threshold was far in excess of the amount actually dispensed by the pharmacy. Cardinal also checked the status of prescribers' medical licenses, though the memorandum does not name the doctors whose licenses were checked or reference the September 2008 discovery regarding Dr. Hoover.[783] The site visit memorandum concludes that the visit and findings "support the determination at this time that the pharmacy does not represent a significant risk for diversion."[784]

---

[778] Cardinal Health Inc., Memorandum (Sept. 12, 2008) (On file with Committee). More information regarding Dr. Hoover can be found at *infra* Section VI (B)(2)(c)(i).

[779] *Id.* A summary of proposed testimony states that a special agent of the HHS Office of Inspector General would testify that in 2010 they observed heavy foot traffic outside Dr. Hoover's clinic, and that the clinic had a hot dog stand and convenience area set up in the lobby to feed the groups of people waiting to be seen. *In re Miami-Luken*, U.S. Drug Enforcement Admin., No. 16-13 (Jan. 15, 2016) (Government's Prehearing Statement) (On file with Committee).

[780] Cardinal Health Inc., Memorandum (Sept. 12, 2008) (On file with Committee). More information regarding Dr. Hoover can be found at *infra* Section VI (B)(2)(c)(i).

[781] *See* E-Mail from Staff, Cardinal Health Inc., to Response for SCS-P Retail Independent Pharmacy Questionnaire, Cardinal Health, Inc. (June 23, 2009 10:39 am) (On file with Committee); *see also* Cardinal Health Inc., Memorandum on Hurley Drug Company (June 16, 2009) (On file with Committee).

[782] Cardinal Health, Memorandum on Hurley Drug Company (June 16, 2009) (On file with Committee).

[783] *Id.*

[784] *Id.*

When asked by the Committee about the decision to increase Hurley's hydrocodone threshold from 10,000 dosage units to 155,000 dosage units within a period of three weeks, Cardinal stated:

> Like all customers at that time, Hurley Drug. Co. was subject to Cardinal Health's controlled substance anti-diversion program. Thresholds were adjusted by anti-diversion professionals following a review of the totality of the circumstances, including an analysis of whether the information available to Cardinal Health suggested the pharmacy presented an unreasonable risk of diversion.[785]

ii. Cardinal's Documentation of Threshold Reductions

While Hurley's 155,000-dose threshold was in place, Cardinal was the secondary supplier for the pharmacy. It was not until March 2011, as Cardinal prepared to switch the pharmacy from a secondary to primary customer, that the distributor reduced Hurley's threshold level from 155,000 doses to 66,501 doses.[786]

Cardinal employees initially believed Hurley's drug thresholds would need to be increased to accommodate the change to primary supplier for the pharmacy. Yet after an assessment of the pharmacy's drug usage was completed, Cardinal instead cut Hurley's hydrocodone threshold by more than half—an indication that the prior threshold was higher than appropriate.

For example, in discussing Cardinal's change from being a secondary to the primary supplier for Hurley, one Cardinal employee wrote that they liked to know when the status of a pharmacy is changing so as to "better accommodate the growth factor."[787] This e-mail is reproduced below:

---

[785] Letter from Counsel to Cardinal Health Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).
[786] Cardinal Health Inc., Threshold change history for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).
[787] E-Mail from Pharmacy Business Consultant, Cardinal Health, Inc., to Staff, Cardinal Health, Inc. (Mar. 7, 2011, 12:12 pm) (On file with Committee).

From: [redacted]
Sent: Monday, March 07, 2011 12:12 PM
To: [redacted]
Cc: [redacted] (PD)
Subject: RE: Hurley Drug #80850 DEA [redacted]

[redacted]

I have received the data but have yet to analyze it – from a QRA standpoint we don't make the customers status (ie primary, secondary) – this may be something you want to bring to CCDB's attention – since this is already and existing customer there is no need for QRA approval.

We just like to know when the status of a pharmacy is changing from Secondary to Primary so we can better accommodate that growth factor and that is why you sending us usage is very helpful.

Thank you,

[redacted]

When Cardinal analyzed Hurley's dispensing data for controlled substances, it found that Hurley's total monthly hydrocodone purchases and/or dispensing[788] for the past year averaged 50,953 doses a month.[789] As a result of the usage analysis, Cardinal reduced the threshold limits for eight drugs, including hydrocodone, which was cut by more than half. The following chart, which refers to hydrocodone by its DEA base code 9193 and oxycodone by its DEA base code 9143, shows the threshold adjustments made:[790]

[788] Cardinal was unable to clarify whether the information was related to the pharmacy's purchases or dispensing of controlled substances. *See* Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).
[789] Cardinal Health, Inc., Hurley Drug dispensing analysis, Mar. 1, 2010 to Feb. 28, 2011 (On file with Committee).
[790] *Id.*

Hurley Drug - [redacted] - DC 8
Date Range - 12 Months - 3/1/2010-2/28/2011
Comments - This customer is moving to Primary Status with CAH

Base	Quantity	Avg	Limit	Limit-Avg/Avg	Changes	
1640	43056	3588	2000	-44%	6001	
2737	87990	7333	5000	-32%	9501	
9050	77721	6477	5500	-15%	8001	
2782	52720	4393	3800	-14%	5001	
2783	46220	3852	3700	-4%	5001	
9273	47884	3990	4200	5%	500	off the market
2765	50434	4203	5200	24%	5501	
2925	18579	1548	2500	61%	N/C	
9064	14608	1217	2100	73%	1801	
2885	39924	3327	6000	80%	4001	
2882	231413	19284	44000	128%	25501	
9143	58958	4913	12000	144%	6501	
9193	611434	50953	155000	204%	66501	
9300	9901	825	6000	627%	1501	
9801	1535	128	1000	682%	175	
5000	22978	1915	16000	736%	3001	

The hydrocodone threshold was reduced to 65,001 doses on March 8, 2011, the day after the previously referenced e-mail. This was due to "usage analyzed and TH adjusted," according to comments included in a threshold adjustment chart that Cardinal provided the Committee.[791]

FINDING: Cardinal reviewed Hurley Drug Company's account before the pharmacy's switch from a secondary to primary customer, initially anticipating that thresholds would need to be increased to accommodate growth. However, as a result of the review, Cardinal cut Hurley's hydrocodone threshold from 155,000 to 66,501 dosage units.

As discussed previously, Cardinal reached a settlement with the DEA in May 2012 that required it to make changes to its anti-diversion policies and to establish the LV-TAC to review high volume customers. After the settlement, the frequency of Cardinal's site visits to Hurley increased and it lowered the pharmacy's hydrocodone threshold again. On December 12, 2012, Hurley's hydrocodone threshold was reduced from 66,501 dosage units to 55,005 dosage units.[792] Cardinal's threshold change documentation states the adjustment was made "per LV-TAC review."[793] While Cardinal conducted only two site visits to Hurley between 2008 and August 2012, the company conducted nine site visits to the pharmacy between September 2012

[791] Cardinal Health, Inc., Threshold change history for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).
[792] *Id.*
[793] *Id.*

and October 2014.[794] For reasons the Committee could not determine, Hurley stopped purchasing hydrocodone and oxycodone from Cardinal after 2014. However, the company continued to supply other controlled substances to the pharmacy and conducted additional site visits.[795]

As demonstrated by this case study, for thresholds to detect suspicious orders, they must be able to flag orders that are out of the ordinary for a pharmacy. If thresholds are set so high that a pharmacy could purchase between three to 14 times their typical ordering volumes without hitting a threshold, the threshold cannot be expected to effectively flag suspicious orders. Similarly, if thresholds are set and then not independently evaluated for an extended period of time to ensure that they appropriately match the dispensing patterns of a pharmacy, they cannot be expected to effectively flag suspicious orders.

c. *Case Study on Cardinal Health: Vetting Threshold Increases*

Once thresholds are appropriately set, distributors must document their subsequent justifications for increasing and decreasing thresholds, and investigate the justifications provided by customers who seek to increase their thresholds. Thorough documentation and investigation makes it more likely that a distributor will identify "bad actor" pharmacies, and less likely that diversion of drugs supplied by the distributor will occur.

Between 2006 and 2017, Cardinal Health's top purchaser of hydrocodone and oxycodone products in West Virginia was Family Discount Pharmacy in Mount Gay-Shamrock, West Virginia, population 1,779.[796] Cardinal distributed more than 6.03 million doses of hydrocodone and nearly 800,000 doses of oxycodone to Family Discount between 2006 and 2012.[797]

---

[794] Cardinal Health, Inc., KYC site visit survey detail for Family Discount Pharmacy and Hurley Drug Company, undated (On file with Committee).
[795] *Id.*
[796] Cardinal Health, Inc., Top 10 oxycodone and hydrocodone customers (On file with Committee).
[797] U.S. Drug Enforcement Admin., ARCOS data (On file with Committee).

Cardinal's Distribution to Family Discount Pharmacy[798]	
2006	
Drug	**Dosage Units**
Hydrocodone	151,600
Oxycodone	0
2007	
Hydrocodone	161,400
Oxycodone	16,600
2008	
Hydrocodone	705,600
Oxycodone	129,000
2009	
Hydrocodone	1,361,700
Oxycodone	170,200
2010	
Hydrocodone	1,358,800
Oxycodone	164,500
2011	
Hydrocodone	1,321,300
Oxycodone	183,800
2012	
Hydrocodone	975,380
Oxycodone	129,800
Total	**6,829,680**

FINDING: Between 2006 and 2012, Cardinal Health distributed more than 6.03 million doses of hydrocodone and nearly 800,000 doses of oxycodone to Family Discount Pharmacy in Mount Gay-Shamrock, population 1,779. This amount made the pharmacy Cardinal Health's top purchaser of hydrocodone and oxycodone products in West Virginia between 2006 and 2017.

The Committee requested Cardinal provide information related to threshold changes as well as all documents related to the company's due diligence files for Family Discount's Mount Gay-Shamrock location.[799] According to the records provided and as documented in the chart below, Cardinal adjusted Family Discount's hydrocodone threshold limits a total of 19 times between May 2008 and April 2013.[800]

---

[798] *Id.*

[799] *See Letter* from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to George S. Barrett, Exec. Chairman of the Board, Cardinal Health, Inc. and Michael C. Kaufmann, Chief Exec. Officer, Cardinal Health, Inc., Feb. 15, 2018, *available at* https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215CardinalHealth.pdf.

[800] Cardinal Health, Inc., Threshold Change History for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).

Hydrocodone Threshold Adjustments for Family Discount Pharmacy Mount Gay-Shamrock[801]		
Date of Change	**Initial Monthly Dosage Threshold**	**New Monthly Dosage Threshold**
June 13, 2008	27,000	40,000
June 19, 2008	40,000	66,000
June 25, 2008	66,000	70,000
June 27, 2008	70,000	75,000
July 30, 2008	75,000	90,000
October 31, 2008	90,000	35,000
November 13, 2008	35,000	65,000
November 19, 2008	65,000	75,000
December 3, 2008	75,000	80,000
December 18, 2008	80,000	85,000
December 29, 2008	85,000	110,000
May 22, 2009	110,000	110,005
August 25, 2009	110,005	115,005
August 28, 2009	115,005	110,005
January 21, 2010	110,005	150,005
June 14, 2012	154,500[802]	100,005
July 17, 2012	100,005	75,005
November 12, 2012	75,005	5,005
April 24, 2013	5,005	1

As previously discussed, Cardinal did not issue its first formal standard operating procedures, which included threshold policies, until December 22, 2008.[803] Before those SOPs were adopted, Cardinal complied with its suspicious order monitoring obligations by having

[801] *Id.*

[802] Documents provided by Cardinal Health do not indicate when the hydrocodone threshold was adjusted from 150,005 doses to 154, 500 doses. When asked, Cardinal Health was unable to confirm when the threshold was changed. *See* Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).

[803] Letter from Counsel to Cardinal Health, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Apr. 25, 2018 (On file with Committee).

distribution center employees "identify any orders that appeared excessive in relation to what other customers were buying and/or the customer's purchase history."[804] The new SOPs included policies through which Cardinal established custom thresholds for all customers.[805] The thresholds were established "based on the customer's size and class of trade, using historical controlled substance ordering data for all customers."[806] The policies laid out a process by which Cardinal held orders that surpassed the threshold, collected information from customers, and determined whether the orders should be reported as suspicious.[807]

However, based on documents Cardinal provided the Committee, Cardinal did not consistently document the reason for each threshold adjustment nor does it appear to have applied the same level of scrutiny to each threshold increase. In some but not all cases, Cardinal provided threshold event reports that precipitated threshold adjustments as well as accompanying threshold surveys in which pharmacy personnel answered questions about Family Discount's business. At times, Cardinal also included comments in a threshold adjustment chart provided to the Committee or provided emails or other correspondence that references the pharmacy's thresholds. Because the same level of documentation was not kept for all threshold adjustments, it is unclear what factors were taken into consideration prior to some hydrocodone threshold increases for Family Discount. It is also unclear, at times, whether Cardinal verified explanations provided by Family Discount regarding its increased hydrocodone dispensing.

i. Cardinal's investigation of Dr. Katherine Hoover

Cardinal adjusted Family Discount Pharmacy's hydrocodone threshold 19 times between June 13, 2008, and April 24, 2013, with the pharmacy offering various explanations during this time regarding why it requested a higher threshold limit. Among the explanations provided by Family Discount Pharmacy was that the pharmacy was experiencing an increased need for controlled substances based on an increase in prescriptions written by Dr. Katherine Hoover. Yet, Cardinal did not provide documents to the Committee indicating that it inquired further regarding the reason why a single doctor's prescribing was driving up controlled substance orders, nor did Cardinal reevaluate Family Discount's thresholds after it learned other customer pharmacies refused to fill Dr. Hoover's prescriptions.

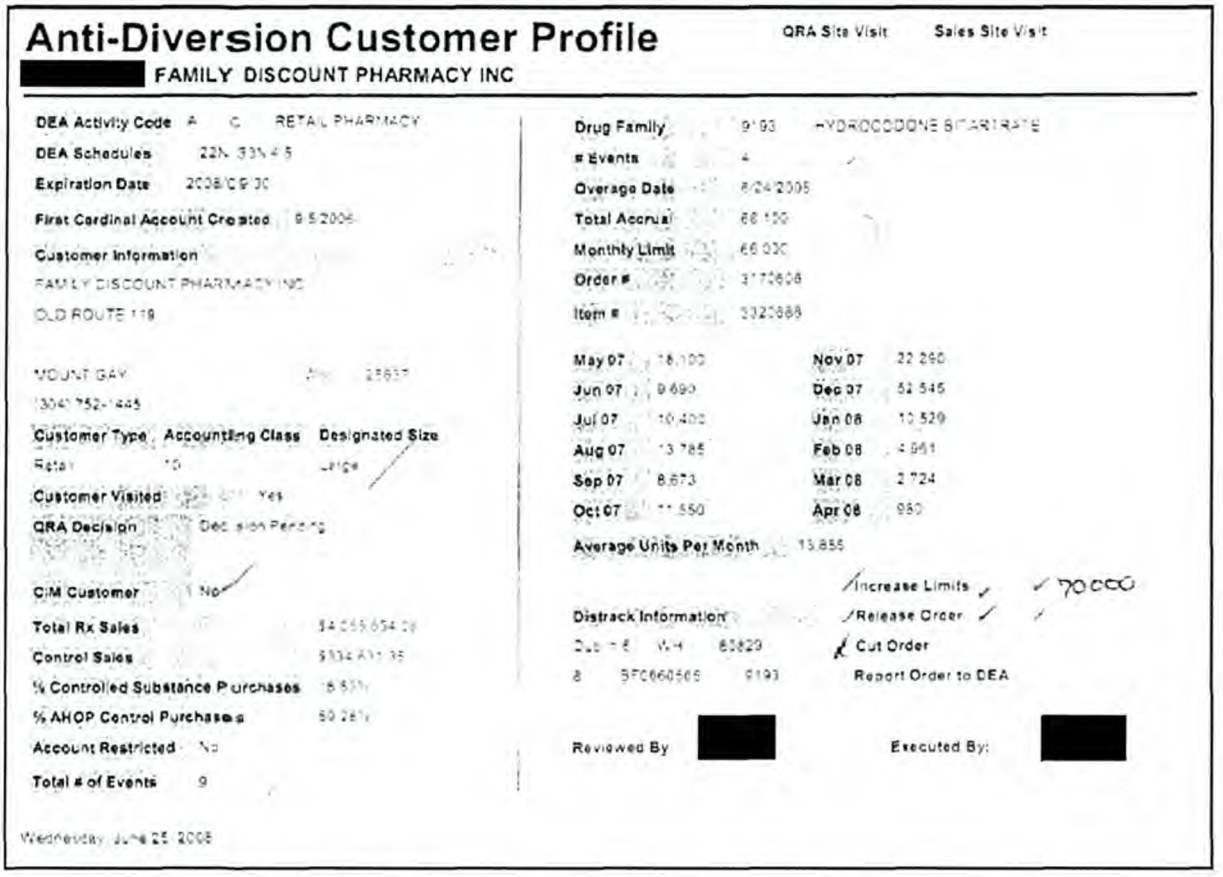
Before increasing Family Discount's hydrocodone threshold for the first time, Cardinal conducted a site visit on June 3, 2008. A one-page memorandum detailing the site visit stated Family Discount drew clients from a 35-mile radius and that two hospitals and doctors' offices were located within two miles of the property.[808] The memorandum also stated the pharmacy had significant business dispensing non-controlled drugs, as well as a moderate amount of

---

[804] *See* Letter from Cardinal Health, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., April 25, 2018 (On file with Committee); *see also* Cardinal Health, Inc., Process to Establish SOM Threshold Limits, Dec. 22, 2008 (On file with Committee).
[805] Cardinal Health, Inc., Process to Establish SOM Threshold Limits, Dec. 22, 2008 (On file with Committee).
[806] Letter from Cardinal Health, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., April 25, 2018 (On file with Committee).
[807] Cardinal Health, Inc. Standard Operating Procedures, Sales – threshold event, Dec. 22, 2008 (On file with Committee).
[808] Cardinal Health, Inc., Memorandum, (June 13, 2008) (On file with Committee).

walk-in traffic, and concluded that "the pharmacy does not represent a significant risk for diversion."[809]

Family Discount hit its hydrocodone threshold four times in June 2008 following the site visit. Each time, Cardinal increased its threshold for hydrocodone. Below is an example of a threshold event dated June 24, 2008. According to the document, Cardinal released the hydrocodone order and increased Family Discount's threshold from 66,000 to 70,000 dosage units.[810]



Anti-Diversion Customer Profile

QRA Site Visit Sales Site Visit

[redacted] FAMILY DISCOUNT PHARMACY INC

DEA Activity Code A C RETAIL PHARMACY
DEA Schedules 2N 3N 4 5
Expiration Date 2008/09/30
First Cardinal Account Created 9/5/2006
Customer Information
FAMILY DISCOUNT PHARMACY INC
OLD ROUTE 119
MOUNT GAY 25637
(304) 752-1445

Customer Type	Accounting Class	Designated Size
Retail	10	Large

Customer Visited Yes
QRA Decision Decision Pending
CIM Customer No
Total Rx Sales $4,055,654.09
Control Sales $334,431.35
% Controlled Substance Purchases 8.5%
% AHOP Control Purchases 89.28%
Account Restricted No
Total # of Events 9

Drug Family 9193 HYDROCODONE BITARTRATE
Events 4
Overage Date 6/24/2008
Total Accrual 66,150
Monthly Limit 66,000
Order # 3170608
Item # 3320888

May 07	18,100	Nov 07	22,260
Jun 07	9,690	Dec 07	52,545
Jul 07	10,402	Jan 08	12,529
Aug 07	13,785	Feb 08	6,961
Sep 07	8,673	Mar 08	2,724
Oct 07	11,550	Apr 08	960

Average Units Per Month 13,855

Distrack Information
Dist # W-H 63829
8 BF0660565 9193

Increase Limits ✓ 70,000
Release Order ✓
Cut Order
Report Order to DEA

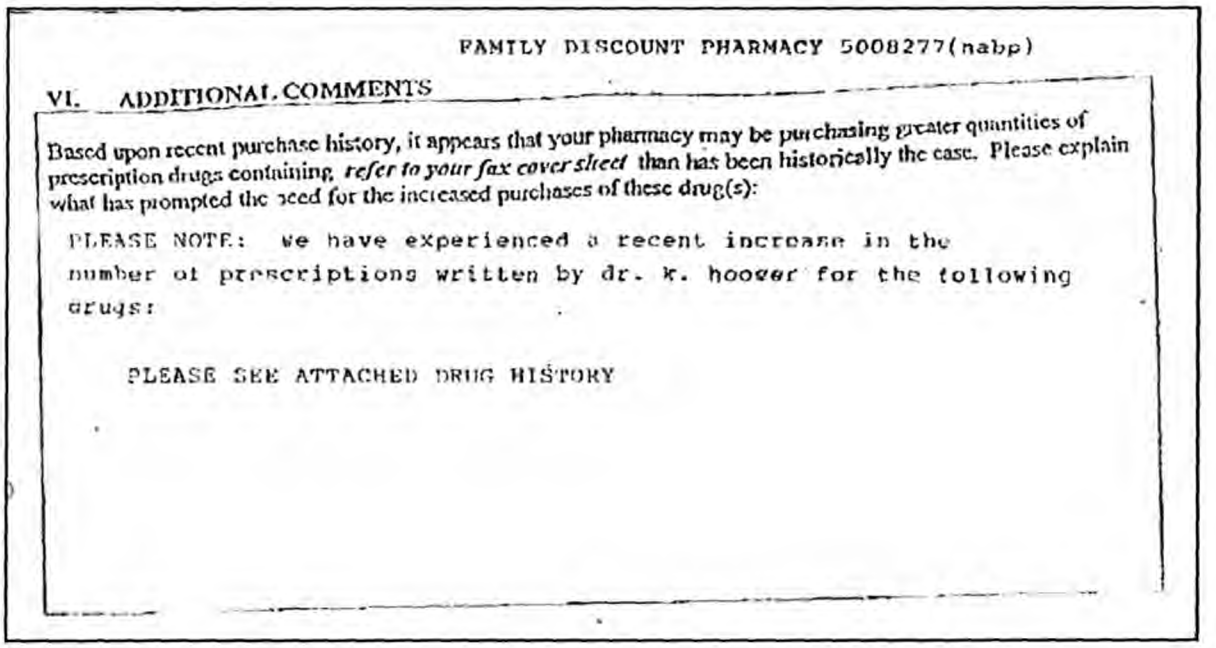
Reviewed By [redacted] Executed By: [redacted]

Wednesday, June 25, 2008

The day after the June 24, 2008, threshold event, Family Discount's pharmacist in charge faxed documentation to Cardinal explaining the pharmacy's increasing need for controlled substances. He wrote that the pharmacy had "experienced a recent increase in the number of prescriptions written by dr. k. hoover"[811] a reference to Dr. Katherine Hoover of Williamson, West Virginia.[812] Based on documents provided to the Committee, this is the

[809] *Id.*
[810] Cardinal Health, Inc., Anti-Diversion Customer Profile for Family Discount (June 25, 2008) (On file with Committee).
[811] Facsimile from Family Discount Pharmacy to Cardinal Health, Inc. (June 25, 2008) (On file with Committee).
[812] Dr. Hoover worked at Mountain Medical Care Center in Williamson, West Virginia, which was raided by federal authorities in 2010 as part of an investigation into pill mill pharmacies. Between December 2002 and 2010, Dr.

earliest explanation Family Discount provided to Cardinal after the June 3, 2008 site visit about the reason for its increased hydrocodone dispensing:[813]



FAMILY DISCOUNT PHARMACY 5008277(nabp)

VI. ADDITIONAL COMMENTS

Based upon recent purchase history, it appears that your pharmacy may be purchasing greater quantities of prescription drugs containing, *refer to your fax cover sheet* than has been historically the case. Please explain what has prompted the need for the increased purchases of these drug(s):

PLEASE NOTE: we have experienced a recent increase in the number of prescriptions written by dr. k. hoover for the following drugs:

PLEASE SEE ATTACHED DRUG HISTORY

In support of the threshold increase request, the pharmacy attached historical drug sales data for six various strengths and formulations of hydrocodone.[814] Despite the pharmacy's reference to an increase in hydrocodone prescriptions written by a single doctor in justifying the request for a controlled substance increase, Cardinal does not appear to have inquired further about Dr. Hoover's prescribing at that time. The documents provided to the Committee do not show any attempt by Cardinal to further investigate Dr. Hoover's prescribing after this disclosure. Cardinal increased Family Discount's hydrocodone threshold to 70,000 dosage

---

Hoover was responsible for writing 355,132 controlled substance prescriptions in West Virginia, more than any other prescriber in the state. *See* Memorandum Opinion and Order, *United States v. $88,029.08, More or Less, in United States Currency*, No. 2:10-cv-1087 (S.D. W.Va. Sept. 28, 2012). While she fled to the Bahamas shortly after the raid, federal authorities seized $88,000 from her, and other physicians who worked at the clinic were criminally charged and received prison sentences. *See* Lawrence Messina, Associated Press, *Doctor seeks $88,000 seized in pill mill probe*, TIMES WEST VIRGINIAN, Dec. 6, 2012, http://www.timeswv.com/news/doctor-seeks-seized-in-pill-mill-probe/article_dac39b98-e59b-5edc-bf5e-c0022b20cb4d.html. Dr. Hoover had a disciplinary history in other states that included two years' probation by the Florida medical board following allegations of inappropriately and excessively prescribing controlled substances, a $1 million payment in a malpractice settlement, and suspension and eventual restoration of her license in West Virginia over a matter not related to controlled substance prescribing. Cardinal Health, Inc., Memorandum (Sept. 12, 2008) (On file with Committee). At least one other distributor viewed her controlled substance prescriptions with concern. H.D. Smith reported its concerns regarding Dr. Hoover's prescribing habits to DEA in April 2008. *See* Letter from Counsel to H.D. Smith Wholesale Drug Co. to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).

[813] Facsimile from Family Discount Pharmacy to Cardinal Health, Inc. (June 25, 2008) (On file with Committee).

[814] *Id.*

units on June 25, 2008, and 75,000 dosage units two days later on June 27, 2008.[815]

FINDING: In June 2008, Family Discount Pharmacy cited an increase in hydrocodone prescriptions written by a single doctor—Dr. Katherine Hoover—in requesting an increase to its thresholds. Based on documents provided to the Committee, Cardinal did not inquire further about Dr. Hoover's prescribing at that time and raised the hydrocodone thresholds for the pharmacy.

As was referenced in the case study for Hurley Drug Company, Cardinal learned in September 2008 that two Kentucky pharmacists would not fill prescriptions for Dr. Hoover based on their concerns regarding her practice.[816] One of the Kentucky pharmacists described "lines of people standing outside, waiting to get in the office."[817] Cardinal conducted an investigation into Dr. Hoover's background and documented the findings in a memorandum included in case files for both Hurley and Family Discount.[818] However, Cardinal does not appear to have inquired about or calculated the percentage of Family Discount's controlled substance prescriptions written by Dr. Hoover. When asked by the Committee, Cardinal said it was "unable to reconstruct the specific information surrounding conversations with either Family Discount Pharmacy or Hurley Drug Company regarding prescriptions by Dr. Hoover."[819] Cardinal did not produce any documentation showing that it reevaluated the threshold limits for Family Discount upon learning about the prescribing practices of Dr. Hoover.

FINDING: In September 2008, Cardinal learned of derogatory information regarding Dr. Hoover, specifically, that two pharmacists in Kentucky would not fill prescriptions for Dr. Hoover based on concerns about her practice. Documents provided by Cardinal do not indicate the company reevaluated Family Discount Pharmacy's hydrocodone thresholds after learning of this information.

In December 2008, Cardinal adopted policies that highlighted "alert signals" for possible diversion, including "practitioners writing a disproportionate share of the prescriptions for controlled substances being filled."[820] The policy demonstrates that Cardinal considered it a red flag if a doctor prescribed a disproportionate amount of a pharmacy's controlled substances. Due diligence documentation provided to the Committee, however, does not indicate that Cardinal undertook a sufficient review of Family Discount's prescribing physicians before raising thresholds. For example, the documents do not give any indication that Cardinal requested or determined the percentage of controlled substance prescriptions written by Dr.

---

[815] Cardinal Health, Inc., Threshold change history for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).
[816] Cardinal Health, Inc., Memorandum (Sept. 12, 2008) (On file with Committee).
[817] *Id.*
[818] *Id.* More information regarding Dr. Hoover can be found at *supra* Section VI (B)(2)(c)(i).
[819] Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018, (On file with Committee).
[820] Cardinal Health, Inc., Sales – Anti-Diversion Alert Signals, Dec. 22, 2008 (On file with Committee).

Hoover or any other doctors identified by the pharmacy as top-prescribing physicians. In contrast, H.D. Smith found after requesting and reviewing dispensing data that at one point in 2009 Dr. Hoover wrote 51 percent of Family Discount's hydrocodone prescriptions.[821]

ii. Cardinal's Investigation of Pharmacy Closures

On multiple occasions, Family Discount cited the closure of or difficulties with another pharmacy as reasons why it needed increased quantities of controlled substances. Documents provided by Cardinal do not indicate whether the company took any action to verify these claims. While it is entirely plausible and legitimate that the closure of or difficulties with a nearby pharmacy could increase controlled substance sales at another pharmacy, a distributor should at a minimum, verify such a justification before approving a threshold increase.

A threshold survey completed by Family Discount on October 20, 2008 cited the closure of a pharmacy in Chapmanville, West Virginia, approximately 12 miles from the Family Discount location in Mount Gay-Shamrock, to justify its increased hydrocodone quantities.[822] The threshold survey is reproduced in relevant part below:

```
Please explain your need for increased quantities of the drug family:
(Enter answer in paragraph form)
[ we have had an increase in the number of prescriptions filled a local
pharmacy (health rite) located in chapmanville wv 25508 has recently closed
for business i have faxed the drug utilizaiton ]

Name of Drug Family held per Regulatory Review:
(Enter text answer)
[ HYDROCODONE 10/650 ]
```

A second threshold event survey submitted two days later on October 22, 2008 for another strength of hydrocodone provided nearly identical information.[823] No documentation provided by Cardinal indicates if the company took steps to verify whether the Chapmanville pharmacy closed or whether its customers were transferring prescriptions to Family Discount. The Committee was unable to determine whether a Health Rite pharmacy in Chapmanville, West Virginia, closed in the October 2008 time period. There is not currently a Health Rite pharmacy in Chapmanville.

On October 31, 2008, Cardinal reduced Family Discount's hydrocodone threshold from 90,000-dosage units to 35,000 dosage units. Documentation provided by Cardinal does not indicate why the threshold was reduced. Cardinal told the Committee that, given the passage of

---

[821] H.D. Smith Wholesale Drug Co., Account Notes – Family Discount Pharmacy (Mount Gay-Shamrock) Apr. 14, 2009 to May 14, 2009 (On file with Committee).
[822] E-Mail from Staff, Cardinal Health, Inc., to Response for HSCS-P Threshold Event, Cardinal Health, Inc. (Oct. 20, 2008, 12:21pm) (On file with Committee).
[823] E-Mail from Staff, Cardinal Health, Inc., to Response for HSCS-P Threshold Event, Cardinal Health, Inc. (Oct. 22, 2008, 9:27 am) (On file with Committee).

time, it is "unable to reconstruct the specific information surrounding the threshold change for Family Discount Pharmacy on or about October 31, 2008."[824]

This decrease, however, was immediately followed by five increases in Family Discount's hydrocodone threshold that brought the monthly allowable distribution above the previous 90,000-dosage threshold.[825] Between November 13, 2008 and December 18, 2008, Family Discount's threshold was increased four times to 85,000 dosage units. Family Discount hit its hydrocodone thresholds on December 17, 2008 and again on December 19, 2008.[826] On December 23, 2008, Family Discount completed another threshold event survey which again cited the closure of the Chapmanville pharmacy.[827] There is no indication in Cardinal's due diligence files for the pharmacy that it validated this explanation. Nevertheless, on December 29, 2008—seven days after Cardinal's SOP was implemented—Cardinal increased the pharmacy's hydrocodone threshold from 85,000 dosage units to 110,000 dosage units. Documentation provided by Cardinal about this threshold increase states only that "data supports quantity."[828]

The closure of the Health Rite Pharmacy in Chapmanville was not the only one cited by Family Discount Pharmacy to Cardinal as a justification for a threshold increase. In October 2009, Family Discount e-mailed Cardinal and asked for a hydrocodone threshold review, writing, "[w]e are in the middle of this month and our quantities continue to increase, therefore I needed some advise [sic] on how to submit a review for our threshold. i [sic] did send a threshold event survey at the end of September 2009."[829] Family Discount also explained that it needed a threshold increase because it received additional customers due to issues with nearby pharmacies.[830] This e-mail is reproduced below:

---

[824] Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).
[825] Cardinal Health, Inc., Threshold Change History for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).
[826] Cardinal Health, Inc., Anti-Diversion Customer Profile for Family Discount, Dec. 17, 2009 and Dec. 19, 2009 (On file with Committee).
[827] Facsimile from Family Discount Pharmacy to Cardinal Health, Inc., Threshold Event Survey, Dec. 23, 2008 (On file with Committee).
[828] Cardinal Health, Inc., Threshold Change History for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).
[829] E-Mail from Staff, Family Discount Pharmacy, to QRA Anti-Diversion, Cardinal Health, Inc., (Oct. 14, 2009, 12:15 pm) (On file with Committee).
[830] *Id.*

From: [redacted]
Sent: Wednesday, October 14, 2009 12:15 PM
To: GMB-QRA-Anti-Diversion
Subject: regulatory review

dear [redacted]

we currently do not have a hold on any drugs, however, at the end of sept 2009, we did receive a hold on hydrocodone, we have several factors that did increase our quantities for the month of september 2009. we are in the middle of this month and our quantites continue to increase, therefore i needed some advise on how to submitt a review for our threshold. i did send a threshold event survey at the end of September 2009.
there is two main reasons for our increased units, there is a kroger pharmacy within walking distance (aprox 500 feet) from our pharmacy location. kroger pharmacy has recently purchased a new computer system, they have experienced much longer wait times due to problems with their new system, and they are also offering the flu shots,
which have also increased pharmacy wait times, we have received numerous customers from krogers(kroger pharmacy at holden wv phone [redacted] also wal mart pharmacy located at the fountain place mall at logan wv 25601, was undergoing remodeling and we received customers from walmart as well. please let me know
what i need to do to update our threshold to avoid any regulatory holds for the end of this month.

please advise

sincerely
[redacted]
family discount pharmacy
[redacted]

In response to Family Discount's request, Cardinal appears to have sought drug usage data from the pharmacy;[831] Cardinal did not increase the pharmacy's thresholds at that time.

Several months later, in January 2010, Family Discount Pharmacy renewed its request for a hydrocodone increase and provided hydrocodone dispensing data, citing the same customer service problems at the Kroger pharmacy.[832] There is no indication in the documents produced to the Committee that Cardinal attempted to verify Family Discount's claim regarding the Kroger pharmacy, or its previous claim about the Walmart pharmacy, by visiting the sites or otherwise. Cardinal raised the pharmacy's hydrocodone threshold from 110,005 dosages to 150,005 dosages in January 2010.[833]

[831] E-Mail from QRA Anti-Diversion, Cardinal Health to Employee of Cardinal Health, Inc., (Oct. 14, 2009, 12:22 pm) (On file with Committee).
[832] Facsimile from Family Discount Pharmacy to Cardinal Health, Inc. (Jan. 18, 2010) (On file with Committee).
[833] Cardinal Health, Inc., Threshold Change History for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).

FINDING: **On at least three occasions, Family Discount Pharmacy cited the closure of another pharmacy as a reason why it needed increased quantities of controlled substances. Documents provided by Cardinal do not indicate whether the company took any action to verify these claims.**

iii. Family Discount Pharmacy's Frustration with Thresholds

Cardinal also appeared to be under internal pressure from its own sales employees to increase thresholds. Concerns regarding the pharmacy's frustration with thresholds were raised after Family Discount hit its threshold for alprazolam on April 29, 2009. In a May 1, 2009 e-mail discussing the suspicious order monitoring check for the threshold event, a Cardinal sales manager wrote that the customer "has become frustrated with the repeated SOMs and feels he has provided detailed information to justify his orders."[834] This e-mail is reproduced below:

From: [redacted]
Sent: Friday, May 01, 2009 8:59 AM
To: GMB-QRA-Anti-Diversion
Cc: [redacted]; [redacted]
Subject: FW: [SOMStatus] Status Change Notification

We have submitted utilization reports and questionnaires are filled out, a site visit has been made previously, however, thresholds are not adjusted to coincide with monthly usage. This account has become very frustrated with the repeated SOM's and feels he has provided detailed information to justify his orders.

Thanks,
[redacted]

In April 2010, a Cardinal pharmacy business consultant e-mailed other Cardinal employees indicating the company had concerns about losing Family Discount's business to a competitor due to delays caused by its threshold system.[835] Referencing two threshold events that occurred in December 2009, a month before the company raised the hydrocodone threshold to 150,005 dosages, the Cardinal employee wrote, "we were at risk of losing Family Discount as a customer because of this interruption in service."[836] This e-mail is reproduced below:

[834] E-Mail from Sales Manager, Cardinal Health, Inc., to Sales QRA Anti-Diversion Team, Cardinal Health, Inc. (May 1, 2009, 8:59 am) (On file with Committee).
[835] E-Mail from Pharmacy Business Consultant, Cardinal Health, Inc., to Staff, Cardinal Health, Inc. (Apr. 12, 2010, 10:09 am) (On file with Committee).
[836] *Id.*

From: [redacted]
Sent: Monday, April 12, 2010 10:09 AM
To: [redacted]
Cc: [redacted]
Subject: RE: Family Discount Pharmacy
Importance: High

FYI

[redacted]

Here is my info too and I also wanted to provide some background info about why we have set up QRA personal attention to paid to Family Drug Mt Gay, WV. First Family Drug is a very large Independent pharmacy that hit two thresholds in December carrying over into January. The first threshold occurred on a Wednesday which was a day before the holiday and so we didn't deliver on Friday or Saturday and their next normal day was on a Monday. The second blocked order occurred on the exact same day the next week which caused their order to be blocked again and not released then had to be ordered on Monday for Tuesday since everything was reset do to a being a new month they could then get their Meds do to things being reset. These thresholds occurred do to Kroger pharmacy (Avg 350 to 400 RX 's a day) that is across the street installed new pharmacy software which was causing their customers to wait up to 24 hrs to get a prescriptions filled. We were at risk of losing Family Pharmacy as a customer because of this interruption on service and McKesson' s says they are now offering a proactive program to prevent QRA thresholds. I hope this helps to give you some additional info. We have also had a couple of on site visits by [redacted] & [redacted] from QRA team previously. Please let me as we go through this if I can help in anyway.

Thanks,
[redacted]
CARDINAL HEALTH
PHARMACY BUSINESS CONSULTANT

iv. Cardinal's Evaluation and Reduction of Family Discount's Thresholds

As was the case with Hurley, Cardinal began to reduce Family Discount's hydrocodone threshold after the 2012 establishment of the LV-TAC. The LV-TAC was responsible for the "periodic review and scrutiny of large volume purchasers of commonly diverted Controlled Substances or other drugs of interest (ODI) based on existing information in the QRA [Quality and Regulatory Affairs] documents and current purchase patterns."[837] The LV-TAC review procedures took effect on April 12, 2012.[838] Cardinal reduced Family Discount's hydrocodone threshold two months later from 154,500 dosage units to 100,005 dosage units as the result of an LV-TAC decision.[839] Cardinal reduced the pharmacy's hydrocodone threshold again in July 2012 from 100,005 doses to 75,005 doses as a result of another LV-TAC decision, which noted the reductions were "aligned to size of pharmacy."[840] In 2012, Cardinal reported 10 suspicious orders to the DEA regarding Family Discount's orders—all 10 were for hydrocodone and were

[837] Cardinal Health, Inc., Large Volume – Tactical and Analytical Committee Periodic Review Process (Apr. 12, 2012) (On file with Committee).
[838] *Id.*
[839] Cardinal Health, Inc., Threshold Change History for Family Discount Pharmacy and Hurley Drug Company (On file with Committee).
[840] *Id.*

reported after the July threshold reduction.[841] By the end of 2012, Cardinal stopped distributing hydrocodone and oxycodone to Family Discount.[842]

FINDING: After Cardinal formed a Large Volume – Tactical and Analytical Committee, it reviewed and reduced Family Discount Pharmacy's hydrocodone threshold limit from 154,500 dosage units to 75,005 dosage units.

The Committee asked Cardinal whether it performed any independent due diligence in the years prior to these reductions to substantiate the justifications Family Discount provided regarding its requests for threshold increases.[843] Cardinal responded:

> As a retail independent customer of Cardinal Health, Family Discount Pharmacy was subject to Cardinal Health's controlled substance anti-diversion program. From time to time, Family Discount Pharmacy made certain representations to Cardinal Health about changes to its business. In some instances, Cardinal Health would take steps to verify information, for example, by checking records made available on the Board of Pharmacy or DEA website.[844]

Cardinal's due diligence files for Family Discount includes multiple examples of queries through the West Virginia Board of Pharmacy on pharmacy employees as well as DEA registrant profiles.[845] Cardinal also told the Committee it requested dispensing data from customers "from time to time" and would ask pharmacies to identify their top prescribers of controlled substances.[846] When asked by the Committee whether it requested or analyzed dispensing data that identified the corresponding prescribing doctor, Cardinal stated it "does not request for anti-diversion purposes prescription level information revealing the prescriber and patient as that information is protected from disclosure by HIPAA."[847]

---

[841] Cardinal Health has maintained that it has been unable to locate documentation for suspicious orders submitted to the DEA regarding West Virginia pharmacies prior to 2012. Before that time, the company indicated that it reported excessive purchases and concerning customers rather than individual suspicious orders to the DEA. *See* Cardinal Health Inc., Suspicious Orders, 2012 (On files with Committee).

[842] Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).

[843] *See* E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to Cardinal Health, Inc. (Aug. 6, 2018, 3:58 pm) (On file with Committee).

[844] Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).

[845] *See* Cardinal Health, Inc., West Virginia Board of Pharmacy Business Details, Jan. 20, 2008 (On file with Committee); Cardinal Health, Inc., Drug Enforcement Administration registrant profile for Family Discount Pharmacy Inc., Jan. 20, 2008 (On file with Committee).

[846] *See* Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).

[847] Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Sept. 13, 2018 (On file with Committee).

However, in multiple instances Cardinal does not appear to have attempted to validate easily discernable information provided by the pharmacy to justify its request for a threshold increase, such as whether a pharmacy had closed. Moreover, as mentioned above, at least one other distributor requesting dispensing data with prescribers identified, and analyzed the data to identify the percentage of prescriptions written by individual doctors to identify possible red flags. Cardinal's own policies highlight that a high percentage of controlled substances prescriptions written by a single or small group of doctors can be a possible indicator of diversion.[848]

At the Subcommittee's May 8, 2018 hearing, Cardinal's Executive Chairman of the Board, George Barrett, was asked about the degree to which the company vetted threshold increase requests and whether it sought to verify the veracity of justifications provided. He testified:

> Q. When a pharmacy goes over its monthly drug threshold, does Cardinal inquire about the reason for the higher drug order?
>
> A. Thank you, Congresswoman. Today, if an order reaches its threshold, it simply stops. So the process is the threshold is set, and the threshold is set based on a number of factors, the size of the community it serves, not just the population but the community it serves. Other factors. Does it serve a hospice center, a surgical center, et cetera. If an order reaches that threshold, that limit, it simply stops.
>
> Q. But in the past, did it question it, before today?
>
> A. So as I look back at some of the historical documents, I think the thresholds probably should have been set with a different set of eyes. I've mentioned this notion of asking different questions. And I think today we'd probably set those quite differently. But I think at the time of those pharmacies you referred to, thresholds probably should have been adjusted down more quickly.
>
> Q. Did they -- did Cardinal make an assessment as to whether the explanation for increasing its threshold made sense and verified it in any way?
>
> A. It's hard for me to answer that fully. Again, this is part of the history. I have no reason to question the good intent of those doing that kind of assessment. They were professionals. I think they were looking at the incoming order of prescribing. I think now we know some of that prescribing was driven by some behavior that we would have liked to have caught in the physician world. And today that simply

[848] Cardinal Health, Inc., Sales – Anti-Diversion Alert Signals, Dec. 22, 2008 (On file with Committee).

could not happen.[849]

It is critical that distributors maintain records on threshold increases and decreases, and verify justifications provided by a pharmacy to support a threshold increase. If a pharmacy cites a specific doctor as the reason for an increase in controlled substances, the distributor should be able to verify, or at least attempt to verify, the percentage of the pharmacy's prescriptions written by that doctor. Likewise, if a pharmacy cites the closure of another pharmacy as the cause of increased business, the distributor should investigate and document the veracity of that statement. Cardinal's due diligence files for Family Discount included the pharmacy's justifications for why its thresholds should be increased. Based on documents provided to the Committee, however, Cardinal did not clearly document its investigation of those justifications, if any, or its reasons why the thresholds increased or decreased.

d. Case Study on McKesson: Enforcing Thresholds

Even after thresholds are set, vetted, and any subsequent changes are documented and investigated, where necessary, they must be enforced. A failure to do so makes the thresholds essentially meaningless.

In 2006 and 2007, McKesson distributed more than 5.54 million dosages of hydrocodone and more than 204,000 dosages of oxycodone to Sav-Rite No. 1,[850] population 406, in Kermit, West Virginia.[851] The hydrocodone and oxycodone distributions McKesson made in 2006 and 2007 alone were enough that Sav-Rite No. 1 ranked as the company's third largest West Virginia purchaser of those two drugs between all of 2006 and 2017.[852] In 2006, Sav-Rite No. 1 was ranked 22nd in the nation in regard to the overall number of hydrocodone pills it received.[853]

As previously discussed, McKesson launched its "Lifestyle Drug Monitoring Program" (LDMP) in May 2007. This was the first monitoring program implemented by McKesson that utilized thresholds. The purpose of the program was to help identify potential excessive orders and enable the company to work more closely with the DEA, and the program set initial thresholds for all McKesson customers at 8,000 dosages per month for four controlled substance drug families including oxycodone and hydrocodone.[854]

On June 12, 2007, McKesson's counsel wrote to the DEA, confirming that the lifestyle drug monitoring program had been implemented nationwide, stating:

---

[849] *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong at 108 (2018), *available at* https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf.
[850] McKesson Corp., 2006-2017 Sales Data (On file with Committee).
[851] American FactFinder, *Kermit town, West Virginia*, Census 2010 Total Population, *available at* https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml
[852] McKesson Corp., 2006 – 2017 Sales Data (On file with Committee). The largest and second largest customers did business with McKesson for six and twelve years, respectively.
[853] Curtis Johnson, *Big Pill Network Exposed*, HERALD-DISPATCH, Apr. 1, 2009, http://www.herald-dispatch.com/news/recent_news/big-pill-network-exposed/article_8e1791fc-5162-5c36-8bae-6e76bcdb3ec9.html.
[854] McKesson Corp., Lifestyle Drug Monitoring Program, May 15, 2007 (On file with Committee).

> McKesson **has already conducted a level 1 inquiry of all customers** (other than VA hospitals and chain pharmacies) about their distribution practices. These contacts have been documented at each DC. . . McKesson is in the process of conducting a level 2 inquiry with those customers who have placed orders above the expected norm based on the customer's profile and threshold amounts.[855]

The letter appended a copy of McKesson's lifestyle drug monitoring operations manual which showed that a level 1 review would include, among other things, a review of a pharmacy's purchases over a three-month period, an evaluation of whether the purchases were reasonable, and additional investigation if the initial evaluation yielded inconclusive results with respect to the order's reasonableness.[856] The program also required documentation of these evaluations.[857] The Committee infers from McKesson's representation to the DEA that it did, in fact, conduct a level 1 inquiry of all customers, including Sav-Rite No. 1, before June 12, 2007.

However, documentation provided by McKesson indicates that the company continued to ship massive quantities of opioids to Sav-Rite No. 1 even after the implementation of these guidelines and the representation to the DEA that it had completed an initial review of all its customers. In 2007—the very year the lifestyle drug monitoring program was implemented—McKesson sent more than 3 million doses of hydrocodone to the pharmacy.[858] Moreover, this total represents shipments for only a partial year as McKesson terminated Sav-Rite No. 1 as a customer after conducting a site visit on November 14, 2007.[859] The amount of hydrocodone pills McKesson sent to Sav-Rite No. 1 in 2007 equates to an average of 9,650 pills a day, or 289,500 pills a month, which is more than 36 times the threshold amount set that year by the LDMP. Given the volume of hydrocodone pills shipped during this time, it is unclear why it took five months after McKesson's representation to the DEA that a level 1 inquiry of all customers had been completed to conduct a site visit and terminate this pharmacy as a customer.

FINDING: In 2007, McKesson shipped an average of 9,650 hydrocodone pills a day to the Sav-Rite No. 1 pharmacy in Kermit, West Virginia. This was 36 times the threshold amount set by the Lifestyle Drug Monitoring Program.

Notably, and as discussed previously, the entirety of the due diligence file that McKesson produced to the Committee on Sav-Rite No. 1 contained only a single, two-page document—a November 2007 affidavit of James Wooley.[860] The due diligence file did not include any documents regarding the level 1 review or the 8,000 dosage per month threshold imposed by the

---

[855] Letter from Counsel to McKesson Corp., to Linden Barber, Chief, Regulatory Section, Office of Chief Counsel, U.S. Drug Enforcement Admin., June 12, 2007 (emphasis added) (On file with Committee).
[856] McKesson Corp., Lifestyle Drug Monitoring Program, May 15, 2007 (On file with Committee).
[857] *Id.*
[858] McKesson Corp., 2006 – 2017 Sales Data (On file with Committee).
[859] Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Apr. 24, 2018 (On file with Committee). McKesson did not produce any documents to the Committee referring to or otherwise discussing this site visit.
[860] This document is produced in its entirety in Section VI(D)(2)(b)(ii) of this report.

LDMP.[861] The due diligence file also did not include any threshold event documentation indicating that Sav-Rite No. 1 surpassed the threshold, or any documents indicating that the threshold was raised above the 8,000 dosage per month threshold. Based on the documents provided, the Committee also cannot confirm the November 14, 2007, site visit by McKesson to Sav-Rite No. 1, or the reasons for the termination of the pharmacy by McKesson in November 2007.

FINDING: McKesson continued to supply Sav-Rite No. 1 with massive quantities of opioids for five months after representing to the DEA that it had reviewed all customers pursuant to the Lifestyle Drug Monitoring Program.

At the Subcommittee's May 8, 2018 hearing, McKesson President, CEO, and Board Chairman John Hammergren was asked about McKesson's continued shipments to Sav-Rite No. 1 after implementation of the LDMP:

> Q. Now, McKesson started a program in 2007, I think you called it the Lifestyle Drug Monitoring Program, under which McKesson reviewed every single customer for high-volume orders for certain drugs. Is that correct?
>
> A. That's correct.
>
> Q. Including hydrocodone and oxycodone. I think we referenced that in tab 1 in the binder. So the initial threshold, as I understand it, set by McKesson was 8,000 pills a month. The document indicates that you picked that number as a reasonable monthly threshold, correct?
>
> A. That's correct.
>
> Q. And so do you know the average number of hydrocodone dosage units or pills McKesson distributed to that Sav-Rite pharmacy that you terminated a relationship with back in 2007?
>
> A. I do not.
>
> Q. So, we did some research. It appears it's 9,650 pills a day, which averages to 289,500 hydrocodone pills in a 30-day month, which is more than 36 times the initial monthly threshold set by the program.

[861] McKesson later produced a May 2007 e-mail that indicates Sav-Rite No. 1 stood out due to its dispensing volume. This e-mail was not produced in satisfaction of the Committee's February 15, 2018 request that McKesson provide all documents related to McKesson's due diligence file for Sav-Rite No. 1. *See* Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to John H. Hammergren, Chairman, President and Chief Exec. Officer, McKesson Corp., Feb. 15, 2018, *available at* https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215McKesson.pdf. Rather, McKesson's production of the May 2007 e-mail was in response to a supplemental question posed by the Committee on July 31, 2018 regarding a representation McKesson made to the Committee on June 11, 2018. *See* E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).

> The program required distribution centers to review any order in excess of the threshold and document why orders above the threshold were shipped.
>
> Now, according to a document produced by McKesson, all customers had been reviewed by June 12, 2007. This clearly should have identified Sav-Rite, considering your own distribution was 36 times higher than the threshold you set. I think that document's in tab 2. So, did this program identify the Sav-Rite pharmacy?
>
> A. It did not, sir. It should have been terminated sooner.
>
> Q. And if so, on what basis did McKesson decide to continue supplying hydrocodone far above your own threshold? This is what we're trying to figure out.
>
> A. Our systems at the time were not automated enough, certainly, and we didn't flag it fast enough and get it fast enough.
>
> Q. So, are there any documents justifying the continued distribution to Sav-Rite?
>
> A: I don't know, sir. But, as I've testified, we terminated that relationship as soon as we became aware that the purchases were as you described.[862]

Following the hearing, the Committee requested clarification on Mr. Hammergren's answer.[863] In an e-mail to Committee staff, McKesson stated:

> McKesson has not, at this point, been able to identify complete records related to the level 1 review described in its outside counsel's letter to DEA. Nonetheless, McKesson does not currently have information suggesting that Sav-Rite was flagged for further inquiry as part of the level 1 review described in that letter. McKesson personnel did, in May of 2007 (around the same time that the level 1 review was conducted), review data that caused them to flag the pharmacy for follow up. [864]

---

[862] *Combating the Opioid Epidemic: Hearing before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce,* 115th Cong. 60-62 (2018) (testimony of John H. Hammergren, Chairman, President, and CEO, McKesson Corp.) *available at* https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf.

[863] *See* E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (May 23, 2018 1:38 pm) (On file with Committee).

[864] E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (June 11, 2018 7:02 pm) (On file with Committee).

In response to follow-up questions posed by the Committee, McKesson subsequently produced the following e-mails in support of its statement that Sav-Rite No. 1 was flagged by McKesson for follow up:[865]

From: [redacted]
Sent: 5/9/2007 11:34:59 PM
To: [redacted]@mckesson.com]
Subject: FW: Daily Dosage

Today I sat down and went through DC by DC. These two along with Garden in Lakeland really stick out. You and can connect by phone later this week or early next week, I have some thoughts on analysis.

[redacted]

From: [redacted]
Sent: Wednesday, May 09, 2007 4:14 PM
To: [redacted] (Washington Court House)
Cc: [redacted]
Subject: Daily Dosage

[redacted] I have been going through the April Daily Dosage for all DC's. Two of your customers really jumped out at me

Family Discount Phcy
Sav-Rite Phcy

We need to document those ASAP and I would like to understand their business that would drive the numbers

[redacted]

McKesson did not produce additional documents demonstrating what due diligence, if any, McKesson conducted to examine the pharmacy "ASAP," as described in the e-mail. At a minimum, the e-mails indicate that McKesson was aware that Sav-Rite No. 1 was a cause for concern as early as May 2007, yet did not perform a site visit or suspend distribution to the pharmacy until November 2007.

Based on the daily average, between May 2007, when McKesson identified the pharmacy as requiring additional review, and November 2007, when it conducted a site visit, McKesson distributed approximately 2.02 million doses of hydrocodone to the pharmacy. During this entire time, McKesson's threshold for Sav-Rite No. 1 was set at 8,000 dosages of hydrocodone a month.

* * *

While many wholesale distributors have established threshold systems to identify and block customers' suspicious controlled substance orders, the Committee's investigation demonstrates that the formation of threshold guidelines alone does not necessarily prevent overdistribution and diversion. Distributors must ensure thresholds are enforced and conduct

[865] E-Mail from Staff, McKesson Corp., to Staff, McKesson Corp. (May 9, 2007 11:34 pm) (On file with Committee); E-mail from Staff, McKesson Corp., to Staff, McKesson Corp. (May 9, 2007 4:14 pm) On file with Committee).

proper oversight of threshold increase requests and approvals. As shown by H.D. Smith, when distributors do not implement formal threshold systems, they may not detect and investigate rapid increases in controlled substances purchases. McKesson established an 8,000-dosage unit a month threshold for certain highly abusable controlled substances but did not adequately enforce the threshold against a West Virginia pharmacy for months, continuing to ship the equivalent of 9,650 hydrocodone pills a day to the pharmacy. Finally, as demonstrated by Cardinal's handling of two West Virginia pharmacies, distributors need to accurately set threshold limits, as well as document the justifications for increasing or decreasing the thresholds. Distributors should also investigate the justifications provided by customers who seek to increase their drug thresholds. The documentation Cardinal provided to the Committee regarding these two customers does not justify the hydrocodone threshold increases the company approved—a conclusion the company appears to have reached itself years later when it established a task force to review large volume purchasers and subsequently lowered the thresholds of these pharmacies and others.

While the adoption, and implementation, of a threshold system certainly enhances a distributor's ability to know its customer and potentially identify suspicious orders in a more efficient manner, such systems should not be exclusively relied upon to effectively fulfill a distributor's legal obligations to maintain effective controls against diversion and to report suspicious orders when discovered. For example, if a distributor were to exclusively rely on its threshold system to identify suspicious orders, it risks not discovering suspicious activity that may be present, but potentially undetected, if a pharmacy's monthly orders for certain controlled substances do not reach the established threshold levels. As such, a distributor should incorporate its use of thresholds into its overall approach of conducting ongoing, and comprehensive due diligence of its customers that takes into account a variety of different factors, such as the prevalence of drug abuse in a particular area. Such efforts will better enable distributors to identify and report suspicious orders to the DEA, in accordance with their legal obligations.

C. Suspicious Order Reporting by Distributors

1. The Legal Framework Regarding Suspicious Order Reporting

DEA regulations implementing the CSA's closed distribution system require registrants to, among other things, report suspicious orders of controlled substances to the DEA when they are discovered.[866] The Committee's review of suspicious order monitoring programs found the various iterations of these programs distributors had in place in West Virginia did not always result in the required reporting to DEA.

The CSA requires distributors to, among other things, "[maintain] effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[867] In furtherance of this statutory requirement, the CSA's implementing regulations mandate:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.[868]

With respect to the regulation to report suspicious orders, however, in September 2006 and February 2007, the DEA told registrants, "[it] bears emphasis that the foregoing reporting requirement is in addition to, and not in lieu of, the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion."[869]

To address concerns regarding controlled substance diversion, the DEA established the Distributor Initiative Program in 2005. This initiative recognized the role distributors play in the CSA's closed system of distribution and was meant to "educate registrants on maintaining effective controls against diversion, and monitoring for and reporting suspicious orders."[870] As

---

[866] *See* 21 C.F.R. 1301.74(b).
[867] 21 U.S.C. § 823(b)(1) and 21 U.S.C. § 823(e)(1).
[868] 21 C.F.R. § 1301.74(b). The definition of "suspicious" is not limited to orders of unusual size, frequency, or those that deviate substantially from typical ordering patterns. Pursuant to a 2015 order issued by the DEA's Acting Administrator, which has been upheld by the United States Court of Appeals for the District of Columbia Circuit, a pharmacy could have characteristics that "might make an order suspicious, despite the particular order not being of unusual size, pattern or frequency." *See* 80 Fed. Reg. 55,418, 55,473-4, Sept. 15, 2015. *See also Masters Pharmaceutical, Inc. v. U.S. Drug Enforcement Admin.*, No. 15-1335 (D.C. Cir. 2017).
[869] Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Sept. 27, 2006 (On file with Committee); Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Feb. 7, 2007 (On file with Committee).
[870] *Improving Predictability and Transparency in DEA and FDA Regulation, Hearing Before Subcomm. on Health of the H. Comm. on Energy and Commerce,* 113th Cong. Serial No. 113-137, 5 (2014) (statement of Joseph T.

part of the initiative, DEA headquarters officials conducted individual, in-person meetings with some wholesale distributors. The Committee received copies of memorandums regarding the meetings that the agency held with four of the five distributors discussed in this report: AmerisourceBergen, Cardinal, H.D. Smith, and McKesson. Miami-Luken did not have a similar meeting with the DEA. At the meetings, DEA officials reviewed the distributor's legal responsibilities and provided specific examples of the distributor's own customers whose ordering habits and characteristics were suggestive of diversion.[871]

Following the individual distributor initiative meetings, the DEA sent a series of three letters in 2006 and 2007 to every DEA-registered distributor, reiterating distributors' legal obligations to conduct due diligence and report suspicious orders. The initial two letters sent by the DEA in September 2006 and February 2007 provided the same guidance on circumstances which may be indicative of controlled substance diversion. Both letters stated:

> DEA investigations have revealed that certain pharmacies engaged in dispensing controlled substances for other than a legitimate medical purpose often display one or more of the following characteristics in their pattern of ordering controlled substances:
>
> 1. Ordering excessive quantities of a limited variety of controlled substances (e.g. ordering only phentermine, hydrocodone, and alprazolam) while ordering few, if any other drugs
>
> 2. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered
>
> 3. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs

---

Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin) *available at* https://docs.house.gov/meetings/IF/IF14/20140407/102093/HHRG-113-IF14-Wstate-RannazzisiJ-20140407.pdf.

[871] *See* Lenny Bernstein and Scott Higham, *Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control*, WASH. POST, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.af8d3f2847ba. *See also* Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to William J. Walker, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Aug. 16, 2005) (On file with Committee); Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Acting Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Aug. 23, 2005) (On file with Committee); Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Acting Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Dec. 6, 2005) (On file with Committee); Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Jan. 10, 2006) (On file with Committee); and Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Jan. 23, 2006) (On file with Committee).

4. Ordering the same controlled substance from multiple distributors.[872]

The two letters also provided a suggested list of questions that distributors could use as they try to determine whether a suspicious order is indicative of diversion. An excerpt of the letters is reproduced below:[873]

> A distributor seeking to determine whether a suspicious order is indicative of diversion of controlled substances to other than legitimate medical channels may wish to inquire with the ordering pharmacy about the following:
>
> 1. What percentage of the pharmacy's business does dispensing controlled substances constitute?
> 2. Is the pharmacy complying with the laws of every state in which it is dispensing controlled substances?
> 3. Is the pharmacy soliciting buyers of controlled substances via the Internet or is the pharmacy associated with an Internet site that solicits orders for controlled substances?
> 4. Does the pharmacy, or Internet site affiliated with the pharmacy, offer to facilitate the acquisition of a prescription for a controlled substance from a practitioner with whom the buyer has no pre-existing relationship?
> 5. Does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or bona-fide doctor-patient relationship?
> 6. Are the prescribing practitioners licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped, if such a license is required by state law?
> 7. Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?
> 8. Does the pharmacy offer to sell controlled substances without a prescription?
> 9. Does the pharmacy charge reasonable prices for controlled substances?
> 10. Does the pharmacy accept insurance payment for purchases of controlled substances made via the Internet?

Further, the letters emphasized distributors' legal responsibilities as well as the integral role they play in the CSA's closed distribution system.[874]

The third letter, sent on December 20, 2007, addressed suspicious order reporting in a more pointed manner. The DEA explicitly emphasized that the regulations required registrants

---

[872] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. to DEA Registrants, Sept. 27, 2006 (On file with Committee); Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. to DEA Registrants, Feb. 7, 2007 (On file with Committee).

[873] *Id.*

[874] *Id.*

to inform the local DEA Division Office of suspicious orders when they are discovered and underlined this reporting requirement in the letter.[875] The letter stated:[876]

> **The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unit purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.**

The DEA warned registrants that monthly reports, submitted after orders were already filled and sent to customers, would not meet the regulatory requirements, nor would such requirements be met by providing the DEA with daily, weekly, or monthly "excessive purchases" reports.[877] Distributors were urged to take a proactive posture for identifying suspicious orders and were cautioned against relying on rigid formulas.[878] The DEA also informed registrants that it would not endorse a specific system for reporting suspicious orders and that distributors should no longer rely on explicit or implicit approval they may have received from the DEA in the past.[879] The letter stated:

> The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.[880]

DEA's December 2007 letter also referenced an order issued by the DEA's Deputy Administrator in July 2007 that revoked the DEA registration of Southwood Pharmaceuticals, Inc. for failing to meet its obligations under the CSA.[881] Underlying the Deputy Administrator's decision was Southwood's failure to identify and report suspicious orders as well as the company's failure to conduct adequate due diligence.[882] In the order, the Deputy Administrator

---

[875] Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Dec. 20, 2007 (On file with Committee).
[876] *Id.* Section 3292 of the SUPPORT for Patients and Communities Act codified the requirement of suspicious order reporting but not the other requirements upheld in *Masters* on registrants if the suspicious order is shipped. *See* SUPPORT for Patients and Communities Act, Pub. L. No. 115-271 (2018).
[877] Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Dec. 20, 2007 (On file with Committee).
[878] *Id.*
[879] *Id.*
[880] *Id.*
[881] *See* 72 Fed. Reg. 36,504, July 3, 2007.
[882] *See Id.* at 36,487.

rejected Southwood's argument that its submission of ARCOS data was an acceptable substitute for submitting timely suspicious order reports, stating:

> The ARCOS reporting requirement and the suspicious orders reporting requirement serve two different purposes. While ARCOS provides the Agency with information regarding trends in the diversion of controlled substances, the reports need not be submitted until fifteen days after the end of the reporting period. In contrast, as explained above, a suspicious order must be reported "when discovered by the registrant." 21 CFR 1301.74(b). The suspicious order reporting requirements exists to provide investigators in the field with information potential illegal activity in an expeditious manner. Respondent's compliance with the ARCOS reporting requirement is thus not a substitute for its failure to report suspicious orders.[883]

The Deputy Administrator also made clear the company's disclosure of its largest controlled substance purchasers to the DEA was also not an acceptable substitute for submitting timely suspicious order reports, stating:

> Even if [Respondent] had no intent to mislead by submitting these negative reports, Respondent still violated the regulation by failing to report suspicious orders. That some of the pharmacies were identified on the two reports Respondent submitted listing its largest purchasers of controlled substances (which Respondent submitted in February and July 2006), does not excuse its failure to comply with the regulation.[884]

Distributors were also apprised of their responsibility to report suspicious orders at a pharmaceutical industry conference held in September 2007. At the conference, the Chief of DEA's Regulatory Section and AmerisourceBergen's Vice President of Corporate Security and Regulatory Affairs gave a joint presentation on distributors' legal obligations to maintain effective controls against diversion and report suspicious orders when they are discovered.[885] According to a summary of the conference published by DEA, AmerisourceBergen "stressed the importance of knowing your customer, and providing due diligence investigations on all new retail and wholesale accounts, with the exception of retail chain pharmacies."[886]

---

[883] *Id.* at 36,501.

[884] *Id.*

[885] U.S. Drug Enforcement Admin., *Pharmaceutical Industry Conference – September 11 & 12, 2007 – Houston, Texas* (last visited July 10, 2018) *available at* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/13th_pharm/index.html. AmerisourceBergen's presentation at the industry conference came shortly after the company reached a settlement with the federal government on June 22, 2007 to resolve allegations that it failed to meet its obligations and maintain effective controls to prevent controlled substance diversion. As will be discussed in this section, notwithstanding the company's participation in the September 2007 industry conference, the Committee has concerns with respect to AmerisourceBergen's recent suspicious order reporting efforts. *See infra*, Section VI(C)(4).

[886] U.S. Drug Enforcement Admin., *Pharmaceutical Industry Conference – September 11 & 12, 2007 – Houston, Texas* (last visited July 10, 2018) *available at* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/13th_pharm/index.html.

In order to understand the processes by which distributors monitor and report suspicious orders, the Committee requested that AmerisourceBergen, Cardinal, McKesson, H.D. Smith, and Miami-Luken provide copies of any manuals outlining suspicious order monitoring programs or written protocols regarding the identification of suspicious orders.[887] The Committee also requested the companies provide suspicious order reports submitted to the DEA.

The information distributors provided to the Committee demonstrates a variety of interpretations regarding companies' suspicious order report submissions to DEA. McKesson, for example, reported suspicious customers, which it defined as customers it stopped selling controlled substances to, rather than individual suspicious orders to DEA. As a result, McKesson did not submit its first suspicious order report regarding West Virginia pharmacies until 2013. Others like Cardinal Health were unable to provide a comprehensive accounting of suspicious orders reported to DEA, raising questions about the thoroughness of Cardinal's suspicious order monitoring program. AmerisourceBergen began blocking and reporting suspicious orders in 2008 in West Virginia, but after reporting an annual high of 792 suspicious orders in 2013, the company reported just five in 2017. Miami-Luken was found to have no suspicious order monitoring program in place at all and instead allowed employees to make subjective assessments regarding which orders to block and report. H.D. Smith blocked hundreds of hydrocodone and oxycodone orders made by West Virginia pharmacies, but did not report those orders as suspicious because it was instead focused on reporting to DEA customers it terminated. Despite the long-standing legal requirement to report suspicious orders and the supplemental guidance provided by the DEA and a fellow distributor, the documents indicate in West Virginia, that distributors largely failed to meet their legal responsibilities under the CSA.

2. McKesson's Suspicious Order Reporting for West Virginia Pharmacies

From April 2006 through 2016, McKesson supplied more than 299.87 million doses of hydrocodone and oxycodone to West Virginia pharmacies.[888] The Committee requested McKesson provide all suspicious order reports it made to the DEA regarding orders placed by

---

[887] Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Steven H. Collis, Chairman, President and Chief Exec. Officer, AmerisourceBergen Corp., Feb. 15, 2018, *available at* https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215AmerisourceBergen.pdf; Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to George S. Barrett, Executive Chairman of the Board, Cardinal Health, Inc. and Michael C. Kaufmann, Chief Exec. Officer, Cardinal Health, Inc., Feb. 15, 2018, *available at* https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215CardinalHealth.pdf; Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to John H. Hammergren, Chairman, President and Chief Exec. Officer, McKesson Corp., Feb. 15, 2018, *available at* https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215McKesson.pdf; Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to J. Christopher Smith, President and Chief Exec. Officer, H.D. Smith., Jan. 26, 2018, *available at* https://energycommerce.house.gov/wp-content/uploads/2018/01/20180126HDSmith.pdf; Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Dr. Joseph Mastandrea, Chairman of the Board, Miami-Luken, Inc. and Michael Faul, President and Chief Exec. Officer, Miami-Luken, Inc., Jan. 26, 2018, *available at* https://energycommerce.house.gov/wp-content/uploads/2018/01/20180126Miami-Luken.pdf.

[888] Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 27, 2017 (On file with Committee).

West Virginia pharmacies from 2006 to 2017.[889] During this period, and as discussed in greater detail below, McKesson entered into two settlements with the DEA in 2008 and 2017 that required changes to its suspicious order monitoring policies. As a result of changes McKesson made to its policies and procedures during this time, the company did not continuously report the same information to the DEA and could not produce the requested information for the full 11-year period.

FINDING: McKesson Corporation supplied just under 300 million doses of hydrocodone and oxycodone to West Virginia pharmacies between April 2006 and 2016.

DEA met one-on-one with McKesson twice in 2005 and 2006 as part of the agency's Distributor Initiative to discuss drug diversion concerns. A DEA memorandum describes a September 2005 meeting and indicates that DEA briefed McKesson about sales of controlled substances to illicit internet pharmacies, and specifically identified a pharmacy that McKesson was supplying.[890] The memorandum stated:

> During this briefing, McKesson Corporation was provided with information to identify potential illicit Internet pharmacies, advised that hydrocodone, Alprazolam, and Phentermine were the preferred controlled substances in this illicit market, and actions which McKesson Corporation could implement to prevent sales to illicit internet pharmacies.[891]

In January 2006, DEA discussed with McKesson concerns regarding the company's shipment of more than 2 million doses of hydrocodone to six alleged Internet pharmacies over a twelve-day period despite the prior meeting regarding diversion warning signs.[892] DEA officials indicated at the meeting that McKesson might be asked to surrender the registration for its Lakeland, Florida Distribution Center or the DEA would pursue an Order to Show Cause.[893] Amid the backdrop of these interactions with DEA, McKesson began to alter its suspicious order reporting practices.

Prior to 2008, McKesson complied with its suspicious order reporting requirements by submitting "excessive order" reports to the DEA, which were orders that exceeded certain thresholds set by the company.[894] McKesson described these reports as "large hard copy

---

[889] *See* Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to John H. Hammergren, Chairman, President and Chief Exec. Officer, McKesson Corp., Feb. 15, 2018, *available at* https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215McKesson.pdf.

[890] *See* Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Acting Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Dec. 6, 2005) (On file with Committee).

[891] *Id.*

[892] *See* Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Jan. 23, 2006) (On file with Committee).

[893] *Id.*

[894] *See* Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee); Briefing, Staff, McKesson Corp., to Staff, H. Comm. on Energy and Commerce, May 4, 2018.

printouts of individual orders" that were compiled by distribution centers and sent to local DEA offices on a monthly basis.[895] It was not until April 2008 that McKesson began to block suspicious orders that exceeded monthly thresholds.[896] As stated above, the DEA's letters to McKesson and other distributors made clear that filing excessive order reports does not satisfy a distributor's legal obligation to report suspicious orders.[897]

McKesson entered into a $13.25 million settlement and an administrative memorandum of agreement with the DEA in May 2008 to resolve allegations that several of its distribution centers violated their legal obligations by failing to report suspicious orders, as required by 21 C.F.R. § 1301.74(b).[898] When the Department of Justice announced DEA's 2008 settlement with McKesson regarding its alleged failure to report suspicious orders, authorities noted McKesson's continued shipment of controlled substances to illicit internet pharmacies despite the Distributor Initiative warnings:

> Three McKesson distribution centers received and filled hundreds of suspicious orders placed by pharmacies participating in illicit Internet schemes, but failed to report the orders to DEA. They did so even after a Sept. 1, 2005, meeting at which DEA officials met with and warned McKesson officials about excessive sales of their products to pharmacies filling illegal online prescriptions. The pharmacies filled purported online "prescriptions" for hydrocodone (contained in drugs such as Vicodin), but the prescriptions were issued outside the normal course of professional practice and not for a legitimate medical purpose.[899]

McKesson told the Committee that, while this settlement was being finalized, "certain local DEA offices communicated to McKesson that it should stop sending 'excessive order' reports because they were inundating the local DEA office fax machines and were not useful."[900] Instead of sending reports of excessive orders, McKesson said it understood the DEA wanted the company "to identify problematic pharmacies and report those pharmacies to DEA."[901] However, the administrative memorandum of agreement subsequently filed in the settlement states that, among other things, McKesson would maintain a compliance program that included

---

[895] Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).
[896] Briefing, Staff, McKesson Corp. to Staff, H. Comm. on Energy and Commerce, May 4, 2018.
[897] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Dec. 20, 2007 (On file with Committee).
[898] *In re McKesson*, Settlement and Release Agreement and Administrative Memorandum of Agreement, May 2, 2008 (On file with Committee).
[899] U.S. Dept. of Justice, *McKesson Corporation Agrees to Pay More than $13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription Medications*, May 2, 2008, *available at* https://www.justice.gov/archive/opa/pr/2008/May/08-opa-374.html.
[900] Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).
[901] *Id.*

procedures to review orders for controlled substances and report suspicious orders to the DEA. According to the memorandum of agreement:

> Orders that exceed established thresholds and criteria will be reviewed by a McKesson employee trained to detect suspicious orders for the purposes of determining whether (i) such orders should not be filled and reported to the DEA or (ii) based on a detailed review, the order is for a legitimate purpose and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels.[902]

The agreement further stipulated that McKesson should inform DEA headquarters of suspicious orders rather than the local DEA field divisions.[903]

In 2008, McKesson substantially revised its Controlled Substance Monitoring Program (CSMP), including the adoption of a new policy to report suspicious customers to the DEA instead of reporting individual orders.[904] McKesson defined suspicious customers as being those that it had terminated.[905] Documents McKesson identified as its 2008 CSMP operations manual, however, do not explicitly state that only terminated customers will be reported. Rather, the policy is broader and included suspicious orders, transactions, and customers.[906] The policy is reproduced below:

---

[902] *In re McKesson*, Settlement and Release Agreement and Administrative Memorandum of Agreement, May 2. 2008 (On file with Committee).
[903] *In re McKesson*, Settlement and Release Agreement and Administrative Memorandum of Agreement, May 2. 2008 (On file with Committee).
[904] *See* Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee); Briefing, Staff, McKesson Corp. to Staff, H. Comm. on Energy and Commerce, May 4, 2018.
[905] *See* Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee); Briefing, Staff, McKesson Corp. to Staff, H. Comm. on Energy and Commerce, May 4, 2018.
[906] *See* McKesson, Controlled Substance Monitoring Program, First version drafted Feb. 11, 2008, (On file with Committee). The Committee asked McKesson to produce copies of the CSMP operating manual used in each year between 2006 through 2017. McKesson identified this document as its 2008 CSMP, though the document incorporates 43 revisions made through Sept. 24, 2013. The revisions are noted in a log at the end of the document, and indicate what section was changed and when.

6. DEA Reporting Requirements

As per the McKesson/DEA agreement, McKesson will provide the following information to the DEA:

- On a daily basis, McKesson will report any controlled substance transactions/customer that is deemed "suspicious". This process will be performed centrally by the Directors of Regulatory Affairs.
- On a monthly basis, McKesson will provide reports of all non-reportable controlled substance transactions.

6.1 Suspicious Order / Customer Reporting

If at any time a customer or customer transaction is discovered and deemed to be "suspicious", that customer shall be reported to the appropriate Director of Regulatory Affairs. The Regulatory Affairs department will notify the appropriate DEA offices and provide to them any required information.

Distribution centers will be directed to contact their local DEA field offices to report the suspicious customer/transaction as needed by their regional DRA.

Suspicious orders/transactions/customers can be discovered by way of the Level 1, 2, 3 process, DC partner input and/or sales interaction.

Though the CSMP states the company will, on a daily basis, "report any controlled substance transactions/customer that is deemed 'suspicious,'"[907] McKesson said it was not the company's practice at that time to report suspicious orders to the DEA. McKesson told the Committee that "[w]hile orders that exceeded monthly thresholds were blocked under the program, those blocked orders were not reported to DEA as 'suspicious.'"[908] The chart below details the number of hydrocodone and oxycodone orders from West Virginia pharmacies that McKesson blocked but did not report to DEA between May 19, 2008 and July 30, 2013.[909] McKesson began reporting suspicious orders to the DEA on August 1, 2013, so the chart only reflects orders blocked before that time.

[907] *See* McKesson, Controlled Substance Monitoring Program, First version drafted Feb. 11, 2008 (On file with Committee).
[908] Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).
[909] McKesson Corp., West Virginia pharmacy hydrocodone and oxycodone orders McKesson did not ship (On file with Committee).

West Virginia Hydrocodone and Oxycodone Orders Blocked by McKesson[910]							
2006	2007	2008[911]	2009	2010	2011	2012	2013[912]
0	0	300	322	234	221	541	316

McKesson told the Committee that, after the 2008 settlement, it reviewed its revised CSMP with DEA, including its plan to focus on reporting suspicious customers instead of suspicious orders.[913] According to McKesson, "DEA does not appear to have raised concerns about the program's design or its focus on suspicious customers at that time."[914] The Committee was not able to verify this statement through documents produced by McKesson.

However, McKesson's plan to report suspicious customers instead of suspicious orders ran counter to the plain and unambiguous text of the regulation which requires distributors to report suspicious orders when they are discovered.[915] In addition, McKesson's plan to focus on reporting suspicious customers was proposed just a few months after the company received the December 2007 letter from the DEA wherein the agency highlighted the legal requirement to report suspicious orders "when discovered" – a phrase underlined for emphasis in the letter.[916] The DEA letter also advised distributors that the agency would not approve or endorse a particular system for reporting suspicious orders and that it was incumbent upon the distributors to satisfy their legal obligations.[917] McKesson's plan to satisfy its legal requirements by reporting suspicious customers was also contrary to DEA precedent, as stated in the July 3, 2007 Deputy Administrator Order, which expressly rejected alternate types of reporting other than the timely reporting of individual suspicious orders.[918]

From 2008 through July 2013, McKesson did not submit any suspicious order reports to the DEA with respect to orders placed by West Virginia pharmacies. In documents provided to the Committee, the earliest suspicious order McKesson reported to the DEA regarding a West Virginia pharmacy was made on August 1, 2013.[919]

---

[910] *Id.*
[911] McKesson Corp. began blocking orders on May 19, 2008, so this represents a partial year.
[912] McKesson began reporting orders to the DEA on August 1, 2013, so this represents a partial year.
[913] Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).
[914] *Id.*
[915] *See* 21 C.F.R. 1301.74(b).
[916] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Dec. 20, 2007 (On file with Committee).
[917] *Id.*
[918] *See* 72 Fed. Reg. 36,487, July 3, 2007.
[919] McKesson Corp., West Virginia Suspicious Orders Reported to the DEA 2013 – 2017 (On file with Committee). The Committee's review of material obtained during its investigation indicates that McKesson's failure to report suspicious orders to the DEA was not limited to West Virginia. The Committee requested that McKesson provide

FINDING: McKesson did not submit suspicious order reports to the DEA regarding orders placed by West Virginia pharmacies until August 1, 2013.

Between August 1, 2013, and December 18, 2017, McKesson submitted over 10,000 suspicious order reports to the DEA related to orders placed by West Virginia pharmacies.[920] Between 2006 and 2012, the years in which McKesson did not submit any suspicious order reports to the DEA, the company shipped more than 162.6 million doses of hydrocodone and oxycodone to pharmacies in West Virginia.[921] The chart below details the number of suspicious order reports submitted to DEA regarding West Virginia pharmacies as well as the amount of oxycodone and hydrocodone doses shipped to the state each year.

Suspicious Order Reports Submitted by McKesson to the DEA[922]											
2006	2007	2008	2009	2010	2011	2012	2013*	2014	2015	2016	2017**
0	0	0	0	0	0	0	992	3,346	2,603	1,954	1,148
Number (in Millions) of Oxycodone and Hydrocodone Doses Shipped to West Virginia[923]											
17.07	25.63	23.67	22.76	22.16	24.94	26.42	27.92	32.03	40.71	36.53	---

* Documents provided to the Committee indicate that McKesson submitted its first suspicious order report to DEA regarding a West Virginia pharmacy on Aug. 1, 2013, thus, the number of reports in 2013 represents a partial year.
** McKesson provided suspicious order reports through December 18, 2017; thus, the number of suspicious orders reported in 2017 represents a partial year.

FINDING: Between August 1, 2013, and December 18, 2017, McKesson submitted over 10,000 suspicious order reports to the DEA related to orders placed by West Virginia pharmacies.

---

the five states with the highest number of suspicious orders that McKesson reported to the DEA for each year between 2006 and 2017. *See* Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to John H. Hammergren, Chairman, President and Chief Exec. Officer, McKesson Corp., Feb. 15, 2018, *available at* https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215McKesson.pdf. McKesson failed to provide the Committee with any statistics for suspicious orders reported between 2006 and 2010, suggesting that no suspicious orders were reported in that timeframe. In 2011 and 2012, McKesson reported a very low number of suspicious orders to the DEA. *See* McKesson Corp., States with the Highest Number of Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee).

[920] *See* McKesson Corp., West Virginia Suspicious Orders Reported to the DEA 2013 – 2017 (On file with Committee).

[921] *See* Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 27, 2017 (On file with Committee).

[922] McKesson Corp., West Virginia Suspicious Orders Reported to the DEA 2013 – 2017 (On file with Committee).

[923] Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 27, 2017 (On file with Committee). McKesson produced shipment data from April 2006 through the end of 2016.

McKesson began reporting suspicious orders and revised its suspicious order monitoring system after the company came under investigation by the DEA, suggesting to the Committee that the change was prompted by this enforcement action. Documents obtained by the Committee show that the DEA was actively investigating McKesson in early 2013,[924] and the agency served McKesson with an Administrative Inspection Warrant and an Administrative Subpoena on March 12, 2013 in order to obtain records from the company's Aurora, Colorado distribution facility, in furtherance of a possible ISO.[925] That same year McKesson began reporting suspicious orders to the DEA in West Virginia and also "devoted substantial resources to enhance and revise its CSMP."[926] In a letter to the Committee, McKesson described six subject areas in which it has made improvements to its CSMP since 2013. Those areas include: an expansion of its compliance team, additional customer due diligence, advanced threshold analytics and suspicious order reporting, ongoing oversight, customer education, and collaboration with federal and state authorities.[927]

FINDING: McKesson devoted "substantial resources to enhance and revise" its Controlled Substance Monitoring Program in 2013, the same year the DEA served the distributor an Administrative Inspection Warrant and an Administrative Subpoena to obtain records from its Aurora, Colorado distribution facility.

McKesson has continued to update its policies in conjunction with enforcement activities from the DEA. In January 2017, McKesson entered into another administrative memorandum of agreement with the DEA and agreed to pay a record-setting $150 million civil penalty. As part of the settlement, the company accepted responsibility for failure to abide by the terms of the 2008 settlement agreement, including by failing to report suspicious orders to the DEA that should have been identified as suspicious "at various times" between January 1, 2009 and January 17, 2017.[928]

The settlement again required McKesson to send daily suspicious order reports to DEA headquarters rather than division offices and obligated McKesson to "maintain a compliance program intended to detect and prevent diversion of controlled substances."[929] A 36-page compliance addendum attached to the settlement includes other requirements, such as

---

[924] E-Mail from Legal Assistant, U.S. Drug Enforcement Admin., to Section Chief, Pharmaceutical Investigations Section, U.S. Drug Enforcement Admin., et al. (Feb. 5, 2013 1:53 pm) (On file with Committee).
[925] U.S. Drug Enforcement Admin., *Significant Enforcement Activity Report (SEAR Number: SEAR-2013-00643)*, Mar. 15, 2013 (On file with Committee).
[926] Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).
[927] *See Id.*
[928] *In re McKesson*, Settlement Agreement and Release, Jan. 17, 2017, *available at* https://www.justice.gov/opa/press-release/file/928471/download.
[929] *Id.*

maintaining documentation regarding the onboarding of new customers and threshold change requests, and it required McKesson to block and not ship the orders it identifies as suspicious.[930]

Updates were also made to McKesson's CSMP manual in May 2017. The most recent version of the CSMP manual regarding independent and small-to-medium chain retail pharmacies that McKesson provided to the Committee states that all controlled substance orders that exceed a customer's monthly threshold cap are blocked and flagged.[931] At the end of each business day, all flagged orders are compiled in a suspicious order report that is transmitted to DEA headquarters.[932]

McKesson did not report suspicious orders for West Virginia customers until 2013. Since it began doing so, the company submitted upwards of 10,000 suspicious order reports to the DEA. By not reporting suspicious orders when they were discovered, McKesson failed to meet its responsibilities under the CSA. In addition, the failure to report suspicious orders deprived the DEA of timely information that could have alerted the agency to potential controlled substance diversion, which the agency could have used to act against registrants that were illegally diverting controlled substances.

3. Cardinal Health's Suspicious Order Reporting for West Virginia Pharmacies

Cardinal Health distributed approximately 366 million doses of hydrocodone and oxycodone to West Virginia pharmacies between 2005 and 2016, making it the state's largest supplier of controlled substances out of the companies examined as part of the Committee's investigation.[933] The Committee requested that Cardinal provide all suspicious order reports it made to the DEA regarding orders placed by West Virginia pharmacies between 2006 and 2017, as well as policies and procedures related to suspicious order monitoring.[934]

FINDING: Cardinal was West Virginia's largest supplier of oxycodone and hydrocodone between 2005 and 2016, distributing approximately 366 million doses during that time.

---

[930] *In re McKesson*, Compliance Addendum, Jan. 17, 2017, *available at* https://www.justice.gov/opa/press-release/file/928481/download.
[931] McKesson, ISMC Controlled Substance Monitoring Program Operating Manual, May 17, 2017 (On file with Committee).
[932] *Id.*
[933] Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, June 30, 2017 (On file with Committee).
[934] *See* Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to George S. Barrett, Exec. Chairman of the Board, Cardinal Health, Inc. and Michael C. Kaufmann, Chief Exec. Officer, Cardinal Health, Inc., Feb. 15, 2018, *available at* https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215CardinalHealth.pdf.

In response to the Committee's request, Cardinal produced spreadsheets detailing suspicious order reports made to the DEA from January 2012 through September 2017.[935] Cardinal told the Committee that, prior to 2012, the company "reported to DEA concerning customers to whom it had ceased distribution of controlled substances based on concerns about potential diversion."[936] Cardinal also told the Committee that it consolidated its suspicious order reporting into one system in 2012 and therefore could not produce comprehensive suspicious order reporting data prior to that time.[937] From 2006 to 2011, the time period for which Cardinal was unable to provide comprehensive data regarding suspicious order reporting in West Virginia, the company distributed approximately 174 million doses of hydrocodone and oxycodone to the state.[938] The below chart details the suspicious orders Cardinal could confirm it submitted to the DEA regarding West Virginia pharmacies from January 2012 through September 16, 2017. During this time, Cardinal submitted more than 2,000 suspicious order reports regarding purchases of all controlled substances.

Suspicious Order Reports Submitted by Cardinal to the DEA[939]											
2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017**
0	0	1*	0	0	0	245	542	557	285	260	181
Number (in Millions) of Oxycodone and Hydrocodone Doses Shipped to West Virginia[940]											
23	24	27	28	36	36	36	31	32	40	34	---

* This suspicious order report was identified by the Committee during its review.
** Cardinal provided suspicious order reports through September 16, 2017; thus, the number of suspicious orders reported in 2017 represents a partial year.

The Committee identified a small number of suspicious order reports submitted by Cardinal to the DEA prior to 2012 in the due diligence files the Committee requested for specific West Virginia pharmacies. For example, Cardinal produced a suspicious order report it submitted to DEA regarding Hurley Drug Company's attempted purchase of 8,000 doses of alprazolam in November 2008.[941] The report sent to DEA indicated the pharmacy's alprazolam threshold was set at 5,000 doses at that time and the entire order was blocked. Another

[935] Cardinal Health, Inc., West Virginia Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee).
[936] Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Apr. 25, 2018 (On file with Committee).
[937] *See* Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Apr. 25, 2018 (On file with Committee).
[938] Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, June 30, 2017 (On file with Committee).
[939] Cardinal Health, Inc., West Virginia Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee).
[940] Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, June 30, 2017 (On file with Committee).
[941] Facsimile from Cardinal Health, Inc. to Drug Enforcement Admin., Charleston Resident Office, Dec. 3, 2008 (On file with Committee)

suspicious order report was submitted to the West Virginia Board of Pharmacy regarding Family Discount Pharmacy's attempted purchase of 18,600 doses of hydrocodone in December 2008.[942] The report indicates that the entire order was blocked.[943]

FINDING: Cardinal did not have a consolidated suspicious order reporting system in place until 2012 and was unable to produce comprehensive suspicious order reports regarding West Virginia pharmacies prior to 2012.

Gaps in Cardinal's suspicious order monitoring program came despite guidance from the DEA on suspicious order reporting obligations. DEA met one-on-one with representatives of Cardinal Health in August 2005 as part of the agency's Distributor Initiative. At the meeting, DEA discussed the characteristics of pharmacies involved in illicit internet sales and provided Cardinal with an example of a Miami, Florida customer to whom the distributor had supplied more than 100,000 doses of hydrocodone a month for three months.[944] After the presentation, Cardinal representatives advised "they would do some research on that account."[945] Cardinal also requested DEA "provide them with as much information as possible concerning the drugs involved, the states that seem to have more Internet pharmacies than others, and anything else that could help them narrow the scope of their review for suspicious orders."[946]

Despite the DEA meeting, Cardinal Health apparently struggled to meet its legal requirements to prevent diversion. Cardinal Health entered into settlement agreements with the federal government on multiple occasions to resolve allegations that it failed to maintain effective controls against diversion and report suspicious orders to the DEA. In 2008, Cardinal agreed to pay a $34 million fine to resolve allegations that several of its distribution centers failed to maintain effective controls and to report suspicious orders to the DEA.[947] The agreement stipulates that Cardinal employees would review orders that hit established thresholds and determine whether they should be blocked and reported to DEA or allowed to be filled.[948] Under the terms of the settlement agreement, Cardinal was required to report suspicious orders to DEA in the following manner:

> Orders that exceed established thresholds and criteria will be reviewed by a Cardinal employee trained to detect suspicious orders for the purposes of determining whether (i) such orders should not be filled and reported to the DEA or (ii) based on a detailed review, the order is for a legitimate purpose

---

[942] Facsimile from Cardinal Health, Inc. to West Virginia Board of Pharmacy, Jan. 16, 2009 (On file with Committee).
[943] *Id.*
[944] Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Aug. 23, 2005) (On file with Committee).
[945] *Id.*
[946] *Id.*
[947] *In re Cardinal Health,* Settlement Agreement, Oct. 2, 2008 (On file with Committee).
[948] *In re Cardinal Health,* Settlement and Release Agreement and Administrative Memorandum of Agreement, Oct. 2, 2008 (On file with Committee).

> and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels.[949]

Cardinal's agreement also described how the company was required it to report suspicious orders to DEA headquarters rather than DEA field offices.[950] The settlement agreement stated, in part:

> Cardinal shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, Cardinal shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters.[951]

Cardinal implemented its first formal standard operating procedures (SOP) in 2008. As previously discussed, among the policies implemented in 2008, Cardinal began using an electronic order monitoring system, which established "custom thresholds for controlled substance distribution for all customers based on the customer's size and class of trade, using historical controlled substance ordering data for all customers."[952] Cardinal's SOP also outlined requirements for, among other things, reporting suspicious orders to DEA and other regulatory bodies, conducting on-site investigations, interactions between the sales team and pharmacy customers, and responding to "highlight reports" that flag customer pharmacies for investigation based on changes in controlled substance sales.[953] The 2008 policy regarding the regulatory notification of suspicious orders required "communication to the DEA about suspicious controlled substances ordering and suspension of controlled substances sales to customers whose orders CAH has deemed suspicious."[954]

Although Cardinal's policies dating back to 2008 required it to notify DEA of suspicious orders, the Committee was unable to determine the frequency with which this occurred in West Virginia prior to 2012 because Cardinal was unable to provide consolidated data regarding suspicious order reporting. The company told the Committee it terminated or suspended shipments of controlled substances to approximately 330 customers across the United States between December 1, 2007 and February 2, 2012.[955]

---

[949] *Id.*
[950] *Id.*
[951] *Id.*
[952] Letter from Counsel to Cardinal Health, Inc. to Staff, H. Comm. on Energy and Commerce, et al., Apr. 25, 2018 (On file with Committee). Cardinal's threshold policies are discussed in further detail in section VI(B)(1)(b).
[953] *See* Cardinal Health, Inc., Sales – Highlight Report, Dec. 22, 2008 (On file with Committee); *see also* Cardinal Health, Inc., Sales - Investigation, Dec. 22, 2008 and Cardinal Health, Inc., Regulatory Notification of Suspicious Orders and/or Suspension of Sales of Scheduled/List 1 Substances, Dec. 22, 2008 (On file with Committee). 3
[954] Cardinal Health, Inc., Regulatory Notification of Suspicious Orders and/or Suspension of Sales of Scheduled/List 1 Substances, Dec. 22, 2008 (On file with Committee).
[955] *See* Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, et al., Apr. 25, 2018 (On file with Committee).

FINDING: Since 2008, Cardinal's policies have required notification of DEA regarding suspicious orders. The company was unable to provide comprehensive data prior to 2012 demonstrating compliance with these reporting policies in West Virginia.

Despite the adjustments made to Cardinal's suspicious order monitoring system, the company's suspicious order monitoring program came under scrutiny by DEA again. In May 2012, Cardinal entered into another settlement with DEA to resolve allegations that its Lakeland, Florida distribution facility did not abide by the terms of the 2008 settlement agreement and that it continued to fail to report suspicious orders to the DEA.[956] As part of the agreement, Cardinal admitted that between the time the 2008 memorandum of agreement took effect and May 14, 2012, it failed to detect and report suspicious orders and failed to conduct due diligence to ensure controlled substances were not diverted.[957] Among the terms and conditions of the settlement, Cardinal was required to maintain a compliance program that would detect and prevent controlled substance diversion, to implement procedures ensuring the company inspected pharmacies where diversion was suspected, and to enhance its procedures for establishing thresholds and its processes for conducting due diligence reviews.[958]

With respect to reporting suspicious orders to the DEA, the settlement again required Cardinal to report suspicious orders to DEA headquarters rather than DEA field offices.[959] The Administrative Memorandum of Agreement stated, in part:

> f. **Cardinal shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, Cardinal shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters. DEA has previously notified all of the DEA Field Offices that Cardinal is not required to provide suspicious order reports or any other type of report regarding suspicious purchases of controlled substances to the DEA Field Offices. Execution of this Agreement by DEA shall waive the DEA regulatory requirements to report suspicious orders to DEA Field Offices for the duration of the Agreement.**

Cardinal issued a "complete rewrite" of its policies related to detecting and reporting suspicious orders and responding to threshold events in April 2012.[960] In an explanation of the changes, Cardinal's policy states the rewrite was done "to properly define the process for detecting and reporting suspicious order and responding to threshold events."[961]

---

[956] *In re Cardinal Health*, Administrative Memorandum of Agreement, May 14, 2012 (On file with Committee).
[957] *Id.*
[958] *Id.*
[959] *Id.*
[960] Cardinal Health, Inc., Detecting and Reporting Suspicious Orders and Responding to Threshold Events, Apr. 12, 2012 (On file with Committee).
[961] *Id.*

FINDING:	**Cardinal issued a "complete rewrite" of its Detecting and Reporting Suspicious Orders and Responding to Threshold Events policy in April 2012. This was done a month before it entered into a settlement agreement with DEA to resolve allegations the company failed to report suspicious orders.**

The policy described orders as suspicious if they were of unusual size, frequency or deviated substantially from a normal pattern for the customer.[962] Cardinal's 2012 policy provided detailed guidance on how to respond to each circumstance and required that any order deemed suspicious must be held and reported to the DEA.[963]

The civil penalties component of the 2012 settlement was resolved in 2016 when Cardinal agreed to pay a $34 million fine as well as another $10 million fine to resolve allegations brought against one of its subsidiaries, Kinray, Inc.[964] Policy updates continued in 2016. While a version of the policy issued in October 2016 included much of the same language describing the initial review of customer orders, it additionally required that a held order be reviewed by Corporate Quality and Regulatory Affairs (QRA) personnel and incorporates the DEA-mandated requirement that threshold adjustments above a certain level require two-person concurrence.[965]

Prior to 2012, Cardinal focused on reporting to DEA customers it suspended rather than individual suspicious orders. According to Cardinal, the company terminated or suspended shipments of controlled substances to approximately 330 customers across the United States between December 1, 2007 and February 2, 2012.[966] The company appears to have been submitting individual suspicious order reports prior to 2012, as demonstrated by documentation included in Family Discount Pharmacy's due diligence files, as discussed earlier. As the 2012 settlement agreement between the DEA and Cardinal made clear, however, the DEA was not satisfied by the level of suspicious order reporting that occurred between 2008 and 2012. Cardinal was unable to provide consolidated report data to the Committee regarding suspicious orders prior to 2012, so it is unclear how frequently such reports were submitted. Cardinal issued revised suspicious order policies in 2012 and between 2012 and 2017, Cardinal submitted more than 2,000 suspicious order reports to DEA regarding West Virginia pharmacies.[967]

---

[962] *Id.*
[963] *Id.*
[964] Press Release, U.S. Dep't of Justice, M.D. Fla., United States Reaches $34 Million Settlement With Cardinal Health For Civil Penalties Under the Controlled Substances Act (Dec. 23, 2016),https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under.
[965] Cardinal Health, Inc., Detecting and Reporting Suspicious Orders and Responding to Threshold Events, Oct. 17, 2016 (On file with Committee).
[966] *See* Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, et al., Apr. 25, 2018 (On file with Committee).
[967] Cardinal Health, Inc., West Virginia Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee).

4. AmerisourceBergen's Suspicious Order Reporting for West Virginia Pharmacies

AmerisourceBergen distributed 248.16 million doses of hydrocodone and oxycodone to West Virginia pharmacies between 2005 and 2016.[968] The Committee requested AmerisourceBergen provide all suspicious order reports submitted to the DEA regarding orders placed by West Virginia pharmacies from 2006 and 2017 as well as policies and procedures related to suspicious order monitoring during that period.[969] AmerisourceBergen told the Committee it had a program in place to monitor and report suspicious orders since at least the 1980s.[970] Contrary to McKesson and Cardinal, AmerisourceBergen began blocking and reporting suspicious orders to the DEA in 2007.

FINDING: AmerisourceBergen distributed nearly 250 million doses of hydrocodone and oxycodone to West Virginia pharmacies between 2005 and 2016.

Two years before AmerisourceBergen began reporting suspicious orders to the DEA, the agency provided guidance to the company on how to comply with its legal obligations. The DEA met one-on-one with AmerisourceBergen in 2005 as part of the Distributor Initiative to discuss characteristics and warning signs of illicit internet pharmacies. A DEA memorandum regarding the August 2005 meeting states that DEA officials discussed distributors' legal responsibilities to report suspicious orders when they are discovered and provided AmerisourceBergen with two examples of internet pharmacies to highlight "the brazenness of activity to which Internet pharmacies will go to."[971]

Prior to July 2007, AmerisourceBergen mailed copies of reports to the DEA on a monthly basis identifying pharmacies that placed orders for controlled substances in excess of thresholds set by the company.[972] Although AmerisourceBergen reported these orders to the DEA, it did not block suspicious orders received from customers prior to July 17, 2007.[973]

Less than a month before AmerisourceBergen began blocking orders, the company reached a settlement with the federal government on June 22, 2007 that resolved allegations that it previously failed to meet its obligations and maintain effective controls to prevent controlled substance diversion.[974] Once AmerisourceBergen began blocking suspicious orders, it also

---

[968] Letter from AmerisourceBergen, Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 30, 2017 (On file with Committee).
[969] *See* Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Steven H. Collis, Chairman, President and Chief Executive Officer for AmerisourceBergen Corp., Feb. 15, 2018, *available at* https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215CardinalHealth.pdf.
[970] *See* Letter from AmerisourceBergen, Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 30, 2017 (On file with Committee).
[971] Memorandum from Michael R. Mapes, Chief, E-Commerce Section, Office of Diversion Control, U.S. Drug Enforcement Admin. to William J. Walker, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (Aug. 16, 2005) (On file with Committee).
[972] Briefing by Staff, AmerisourceBergen Corp. to Staff, H. Comm. on Energy and Commerce, May 4, 2018.
[973] *Id.*
[974] *In re AmerisourceBergen*, Settlement and Release Agreement (June 22, 2007) (On file with Committee).

started submitting suspicious order reports to the DEA when the orders were deemed suspicious, instead of doing so on a monthly basis, including those for orders placed by West Virginia pharmacies.[975]

AmerisourceBergen told the Committee that, in 2007, it created an "enhanced order monitoring program" in "consultation with DEA."[976] According to policies and procedures AmerisourceBergen provided the Committee, the company issued numerous revised policies in June 2007– the same month it reached a settlement with DEA. In testimony at the Subcommittee's May 8, 2018 hearing, AmerisourceBergen Chairman Steven Collis described the interaction the company had with DEA at the time:

> Q. [Has DEA] ever given you any kind of directions or guidelines? You know, I get it if they're outside the rim, you know, and obviously there's something going on. But, I mean, aside from that. Mr. Collis.
>
> A. Well in 2007, we had a lot of discussion with them, and we developed our current controlled substance order monitoring program and with the understanding that this was where they wanted the industry to go to.[977]

The order monitoring program developed in 2007 "consisted of policies and procedures dedicated to diversion control; a team of full-time diversion control employees; Know Your Customer Due Diligence; an Order Monitoring Program; ongoing monitoring and investigations; and training."[978] As part of that program, the company "began to compare orders placed by customers to thresholds" and then block orders determined to be suspicious.[979]

FINDING: In June 2007, AmerisourceBergen reached a settlement with the government to resolve allegations it failed to maintain effective controls to prevent controlled substance diversion. A month later, the company began to block suspicious orders and submit suspicious order reports to the DEA. Prior to July 2007, AmerisourceBergen mailed copies of suspicious order reports to the DEA on a monthly basis but did not block any orders deemed suspicious.

An "excessive/suspicious order investigation program" policy revised in June 2007 states that AmerisourceBergen's Corporate Security and Regulatory Affairs division would review

---

[975] AmerisourceBergen Corp., West Virginia Suspicious Orders Reported to the DEA 2006 – 2017 (On file with Committee).
[976] Letter from AmerisourceBergen, Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 30, 2017 (On file with Committee).
[977] *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the S. Comm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., 115 (2018) (testimony of Steven H. Collis, Chairman, President, and CEO, AmerisourceBergen Corp.), *available at* https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf.
[978] Letter from AmerisourceBergen, Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 30, 2017 (On file with Committee).
[979] Letter from AmerisourceBergen, Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Mar. 19, 2018 (On file with Committee).

controlled substance orders daily to determine which orders exceeded thresholds.[980] The policy required that orders which exceeded thresholds be held and that orders determined to be possibly suspicious were then investigated further, reported to DEA, and not shipped[981]

AmerisourceBergen also issued a new policy in June 2007 on its controlled substance and listed chemical order monitoring program. The policy stated that distribution center managers or compliance coordinators had autonomy to conduct an initial review of orders based on "know your customer guidelines" and were required to understand "how, when and where their DC [distribution center] is reporting suspicious orders to DEA."[982] The policy indicates that the Corporate Security and Regulatory Affairs (CSRA) division would conduct an investigation of an order if it was flagged by the distribution center.[983] Under the policy, all orders identified as suspicious by CRSA would be logged, investigated, and reported to the DEA as suspicious and any subsequent orders for controlled substances from the same drug family would be rejected pending the result of the CRSA investigation[984]

As indicated by the chart below, AmerisourceBergen began to report and block suspicious orders after the OMP took effect in June 2007. The number of suspicious orders reported from West Virginia pharmacies for all controlled substances varied dramatically from year to year. AmerisourceBergen reported 792 orders as suspicious in 2013. However, the company only provided the DEA with three suspicious order reports for West Virginia pharmacies in 2016, all of which related to orders placed by the same pharmacy on a single day.[985] Similarly, AmerisourceBergen only submitted five suspicious order reports to the DEA in 2017 for orders placed by West Virginia pharmacies.[986] Indicating that AmerisourceBergen's suspicious order reporting may have decreased nationwide, in 2017, on a per-capita basis, West Virginia had the second highest number of suspicious orders reported to the DEA by AmerisourceBergen of all states.[987]

---

[980] AmerisourceBergen, Corp., Excessive/Suspicious Order Investigation Program, June 29, 2007 (On file with Committee).
[981] *Id.*
[982] AmerisourceBergen, Corp., Controlled Substance and Listed Chemical Order Monitoring Program, June 30, 2007 (On file with Committee).
[983] *Id.*
[984] *Id.*
[985] AmerisourceBergen Corp., West Virginia Suspicious Orders Reported to the DEA 2007 – 2017 (On file with Committee).
[986] *Id.*
[987] *See* Letter from AmerisourceBergen, Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., May 2, 2018 (On file with Committee). Given that West Virginia accounted for only five suspicious orders in 2017, the Committee asked AmerisourceBergen if the representation made in the Company's May 2, 2018 letter was correct. *See* E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to AmerisourceBergen Corp. (July 23, 2018 3:13 pm) In response, the Company told the Committee that the representations made in its May 2, 2018 letter were accurate. *See* E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 pm).

Suspicious Order Reports Submitted by AmerisourceBergen to the DEA[988]											
2006	2007*	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
0	6	18	60	47	178	311	792	545	53	3	5
Number (in Millions) of Oxycodone and Hydrocodone Doses Shipped to West Virginia[989]											
18.02	20.34	22.34	24.03	16.8	19.94	21.8	20.16	19.89	15.85	11.51	---

* AmerisourceBergen began to report and block suspicious orders in July 2007, thus, the number of suspicious orders reported in 2007 represents a partial year.

FINDING: The number of suspicious order reports regarding West Virginia pharmacies that AmerisourceBergen submitted to DEA and blocked from shipment ranged from a high of 792 orders in 2013 to a low of three orders in 2016.

At times, AmerisourceBergen stopped doing business with a pharmacy following a series of suspicious order reports. For example, 36 of the 60 suspicious order reports made by AmerisourceBergen in 2009 were for orders placed by Tug Valley Pharmacy.[990] The 36 suspicious orders were reported to DEA within a one-month period between September 18, 2009 and October 8, 2009. AmerisourceBergen provided the Committee with documentation showing Tug Valley ordered 108,700 doses of hydrocodone in September 2009, up from 12,500 doses ordered the prior month.[991] A Corporate Security and Regulatory Affairs review was undertaken and determined "that a high percentage of the prescriptions written were from two physicians, both with extensive disciplinary records and prior revocations in other states."[992] AmerisourceBergen stopped doing business with Tug Valley Pharmacy on October 19, 2009 as a result of a Corporate Security and Regulatory Affairs review.[993]

However, in at least two other instances, the number of suspicious orders reported did not cause AmerisourceBergen to take such prompt action. AmerisourceBergen submitted approximately 400 suspicious orders for a single pharmacy, Beckley Pharmacy between 2012 and 2015.[994] Of those suspicious order reports, 199 were reported between November 2013 and

[988] AmerisourceBergen Corp., West Virginia Suspicious Orders Reported to the DEA 2007 – 2017 (On file with Committee).
[989] Letter from Counsel to AmerisourceBergen, Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 30, 2017 (On file with Committee).
[990] AmerisourceBergen Corp., West Virginia Suspicious Orders Reported to the DEA 2007 – 2017 (On file with Committee).
[991] AmerisourceBergen Corp., OMP Activity – Tug Valley Pharmacy – Columbus, Feb. 23, 2010 (On file with Committee).
[992] *Id.*
[993] AmerisourceBergen Corp., Controlled Substances "Do Not Ship" List, last updated Oct. 17, 2017 (On file with Committee).
[994] AmerisourceBergen Corp., West Virginia Suspicious Orders Reported to the DEA 2007 – 2017 (On file with Committee).

March of 2014.[995] Documents provided to the Committee indicate that AmerisourceBergen did not investigate the pharmacy until February 2015, however, at which point the company found numerous red flags of diversion and opted to stop doing business with Beckley.[996]

In another instance, AmerisourceBergen submitted 103 suspicious order reports regarding City Pharmacy in Martinsburg, West Virginia between January 2012 and March 2014. Yet AmerisourceBergen continued doing business with City Pharmacy until April 2014, when the owner, David Wasanyi, was arrested.[997] A second pharmacy, City Pharmacy of Charles Town, was also owned by the same individual but not placed on AmerisourceBergen's "Do Not Ship" list until January 2016.[998] According to a complaint filed in 2016 by the U.S. Attorney's Office for the Northern District of West Virginia, between January 2010 and November 2015, the two pharmacies "filled more than 1,100 prescriptions written by medical providers located in Florida, Georgia, Virginia and Tennessee for individuals residing in Alabama, Florida, Georgia, Kentucky, Maryland, Ohio, Pennsylvania, Tennessee and Virginia."[999]

In a briefing with Committee staff, AmerisourceBergen representatives said there is no rule or policy regarding the number of suspicious order reports that would trigger an investigation of a pharmacy customer.[1000] The company would consider it a problem, however, if a pharmacy continued to get repeated suspicious order reports.[1001]

FINDING: AmerisourceBergen responded inconsistently when pharmacies triggered repeated suspicious orders. In 2009, the company investigated and terminated its relationship with Tug Valley Pharmacy after reporting 36 suspicious orders in one month. However, AmerisourceBergen continued to supply Beckley Pharmacy for nearly a year after reporting 109 suspicious orders in five months from 2013 to 2014.

---

[995] *Id.*

[996] Pharma Compliance Group, Observations and Recommendations Report – Beckley Pharmacy, Feb. 15, 2015 (On file with Committee). AmerisourceBergen reinstated Beckley Pharmacy as a customer in 2016 after a subsequent review determined that several of the concerns leading to its termination had been alleviated and the risk of diversion was reduced. *See, Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (responses to questions for the record submitted by Steven H. Collis, CEO, President and Chairman of the Board, AmerisourceBergen Corp.).

[997] AmerisourceBergen Corp., Controlled Substances "Do Not Ship" List, last updated Oct. 17, 2017 (On file with Committee). . Wasanyi was arrested in April 2014 and later convicted on a series of state charges related to the dispensing of controlled substance prescriptions at his two pharmacies. *In re City Pharmacy, LLC, et al,* U.S. Justice Dept., N.D.W.Va. No. 16-cv-24 (Feb. 29, 2016) (Order on Motion to Dismiss, Motion to Strike Expert Testimony, and Motion on Summary Judgement) (On file with Committee).

[998] AmerisourceBergen Corp., Controlled Substances "Do Not Ship" List, last updated Oct. 17, 2017 (On file with Committee).

[999] *In re City Pharmacy, LLC, et al,* U.S. Justice Dept., N.D.W.Va. No. 16-cv-24 (Feb. 29, 2016) (Complaint) (On file with Committee). In the complaint, prosecutors said Mr. Wasanyi and his co-defendants "should have known that prescriptions for controlled substances, written by medical providers located in distant states, presented by a large number of individuals who traveled together from distant locations were not written for legitimate medical purposes." *Id.*

[1000] Briefing by Staff, AmerisourceBergen Corp. to Staff, H. Comm. on Energy and Commerce, May 4, 2018.

[1001] *Id.*

AmerisourceBergen has continued to update its suspicious order monitoring policies in recent years. The most recent diversion control program policies and procedures manual AmerisourceBergen produced to the Committee was issued in January 2017. The Order Monitoring Program policy requires that AmerisourceBergen reject and report all orders designated as suspicious to the DEA and state authorities, as well as that the company "establish mechanisms to continually monitor drug product trends and customer trends and ordering patterns in order to prevent the diversion of Controlled Substances into other than legitimate medical, scientific, and industrial channels."[1002]

Under the 2017 policies, members of AmerisourceBergen's Diversion Control Team assess whether an order of interest is suspicious based on factors including product information, customer data, and customer ordering history.[1003] The employee will make a determination "based on the totality of the information that is reviewed during investigation of the *Order of Interest*" and, if the order is deemed suspicious, "the order will be rejected and reported to DEA and state authorities, as appropriate."[1004]

As mentioned previously, the number of suspicious order reports AmerisourceBergen submitted to DEA varied widely from year to year. The company told the Committee the variation is due to numerous factors, including a recent decrease in the overall number of opioid prescriptions written, more precise identification of suspicious orders by the company, and efforts to stop selling controlled substances to pharmacy customers that raise concern.[1005] AmerisourceBergen described its efforts to enhance its order monitoring system:

> Over time, as technology has evolved, ABDC has refined the algorithms it uses to identify orders that should be held for additional scrutiny. Additionally, ABDC has worked hard to more precisely identify suspicious orders which it reports to DEA. ABDC developed additional data monitoring and compilation tools, the dashboards referenced in correspondence to the Committee, which allow for greater insight into customer purchasing patterns and history, enabling ABDC to more precisely identify suspicious orders.[1006]

Additionally, AmerisourceBergen told the Committee that it aims to work with trusted customers who share the company's commitment to diversion control and that the company "believes its due diligence and monitoring efforts help eliminate problematic orders from the start, with ABDC ultimately refusing to contract with certain customers, terminating customers,

---

[1002] AmerisourceBergen Corp. Diversion Control Program Policies and Procedures, Order Monitoring Program, Jan. 1, 2017 (On file with Committee).
[1003] AmerisourceBergen Corp. Diversion Control Program Policies and Procedures, Identifying and Reporting Suspicious Orders, Jan. 1, 2017 (On file with Committee).
[1004] AmerisourceBergen Corp. Diversion Control Program Policies and Procedures, Identifying and Reporting Suspicious Orders, Jan. 1, 2017 (Emphasis in original) (On file with Committee).
[1005] *See* E-Mail from Counsel for AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 p.m.) (On file with Committee).
[1006] *Id.*

and limiting customers' ordering – thereby resulting in fewer suspicious orders to be reported."[1007]

AmerisourceBergen's current policies indicate the company will investigate orders that hit thresholds to determine whether they are in fact suspicious and report any such orders to the DEA. Since 2007, the company has actively blocked suspicious orders from West Virginia, but the number of suspicious orders reported to DEA has dropped significantly since 2013. In 2016, the company reported a total of three suspicious orders regarding West Virginia pharmacies yet shipped more than 11 million doses of hydrocodone and oxycodone to the state. While the amount of hydrocodone and oxycodone shipments has also dropped, the decrease has not been proportional to the drop in suspicious orders. The company also indicated that repeated suspicious order reports for a single customer would be considered a problem, yet the Committee identified two instances in which AmerisourceBergen reported more than 100 suspicious orders but continued to supply the pharmacies for an extended period of time. AmerisourceBergen eventually cut off both customers, in one case because an investigation found red flags of diversion, and in another case because the pharmacy owner was arrested.

5. Miami Luken's Suspicious Order Reporting for West Virginia Pharmacies

Miami-Luken was a regional distributor based in Springboro, Ohio that serviced customers in the Midwest and Appalachia. An OTSC the DEA filed against Miami-Luken in 2015 noted the high volume of opioid pills the company sent to pharmacies in West Virginia, including: 683,300 doses of hydrocodone to Sav-Rite Pharmacy No. 1 during July, August and September of 2008; 118,900 doses of hydrocodone to Westside Pharmacy in December 2013; and 95,400 doses of hydrocodone to Family Discount Pharmacy in April 2014.[1008] The Committee requested Miami-Luken provide copies of all suspicious order reports for hydrocodone or oxycodone that were submitted to DEA since 2008.[1009] The company was unable to produce documentation from the full timeframe because it did not have a suspicious order monitoring system until 2015, and did not consistently submit suspicious order reports to the DEA.

Miami-Luken received the three letters issued by DEA in 2006 and 2007 advising distributors of their obligation to report suspicious orders.[1010] According to court documents,

---

[1007] *Id.*

[1008] U.S. Drug Enforcement Admin., *In re Miami-Luken*, Order to Show Cause, Nov. 23, 2015 (On file with Committee).

[1009] Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Joseph Mastandrea, Chairman of the Board, Miami-Luken, Inc. and Michael Faul, President and Chief Exec. Officer, Miami-Luken, Inc., Sept. 25, 2017, *available at* https://energycommerce.house.gov/wp-content/uploads/2017/09/2010925Miami_Luken.pdf.

[1010] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. to DEA Registrants, Sept. 27, 2006 (On file with Committee); Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. to DEA Registrants, Feb. 7, 2007 (On file with Committee) and Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r,

D. Distributors Continued to Ship Opioids to Pharmacies in West Virginia Despite Red Flags of Diversion

1. Obligations of Distributors to Conduct Ongoing Due Diligence and Investigate Suspicious Orders

As part of the CSA's overall mandate to maintain effective controls against diversion,[1064] federal regulations require wholesale distributors to identify and report suspicious orders to the DEA when they are discovered.[1065] However, reporting suspicious orders to the DEA does not, on its own, satisfy distributors' legal obligations to maintain effective controls against diversion and to know their customers. As discussed in greater detail in section VI(A)(1), distributors also have an obligation to conduct meaningful, ongoing due diligence of both their prospective and existing customers in furtherance of section 823 of the CSA's overall mandate to maintain effective controls against diversion. This includes proper investigation of potentially suspicious orders that are shipped to the customer instead of being reported to the DEA as suspicious.

In the July 2007 order revoking the DEA registration of Southwood Pharmaceuticals, the DEA's Deputy Administrator cited the company's continued shipments to pharmacies despite having ample information indicating that diversion was likely as being among the reasons why the company's DEA registration should be revoked, stating, "it is especially appalling that notwithstanding the information Respondent received from both this agency and the pharmacies, it did not immediately stop distributing hydrocodone to any of the pharmacies."[1066]

Later that year, in a December 20, 2007 letter to all distributors, the DEA informed distributors that, if a distributor intends to ship an order it determines to be suspicious, reporting any such order to the DEA, on its own, will not absolve the distributor of their responsibility to maintain effective controls against diversion, stating:

> Registrant must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.[1067]

In the letter, the DEA also warned distributors that they risked having their registration revoked if they reported orders as suspicious but elected to fill them without making a determination that the orders were not being diverted, stating:

[1064] *See* 21 U.S.C. § 823(b)(1) and 21 U.S.C. § 823(e)(1).
[1065] *See* C.F.R. § 1301.74(b).
[1066] 72 Fed. Reg. 36,487; 36,500, July 3, 2007.
[1067] Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Dec. 20, 2007 (On file with Committee).

> **[R]egistrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion.** Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C. §§ 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.[1068]

In the September 2015 order revoking the DEA registration of Masters Pharmaceutical, subsequently upheld by the United States Court of Appeals for the District of Columbia Circuit, DEA's Acting Administrator found that the company failed to report suspicious orders to the DEA despite having information that created a strong suspicion that pharmacies it provided controlled substances to were engaged in diversion.[1069] Significantly, the Acting Administrator rejected the company's argument that suspicious orders are limited only to those that are of unusual size, deviate from a normal pattern, or are of unusual frequency, stating:

> [L]imiting the scope of suspicious orders to only those orders which are of unusual size, deviate substantially from a normal pattern, or are of unusual frequency would have ill-served the CSA's purpose of preventing the "illegal . . . distribution, . . . possession and improper use of controlled substances." 21 U.S.C. 801(2). Under Respondent's view, even if it had acquired actual knowledge (let alone developed a suspicion) that a customer was ordering controlled substances from it for the purpose of diverting them, it would have no obligation to report the order as long as the order was of a usual size, did not deviate substantially from the customer's normal ordering pattern, or was consistent with the usual frequency of the customer's orders. **But even orders that do not fall within the three categories set forth in 21 CFR 1301.74(b) can be diverted. Thus, I agree with the ALJ's reasoning "that a pharmacy's business model, dispensing patterns, or other characteristics might make an order suspicious, despite the particular order not being of unusual size, pattern or frequency.**[1070]

To this point, the D.C. Circuit stated, "[r]eading section 1301.74(b)'s listed characteristics as exemplary rather than exhaustive, DEA reasonably concluded that other indicia may also raise suspicions about an order for controlled substances. That conclusion was entirely consistent with the text of the regulation as well as agency precedent."[1071]

Later in the order, the Acting Administrator stated the relevancy of a customer's business practices was not limited to the definition of what constitutes a suspicious order. Rather,

---

[1068] Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Dec. 20, 2007 (emphasis added) (On file with Committee).
[1069] *See* 80 Fed. Reg. 55,501, Sept. 15, 2015; *see also Masters Pharmaceutical, Inc. v. U.S. Drug Enforcement Admin.*, No. 15-1335 (D.C. Cir. 2017).
[1070] 80 Fed. Reg. 55,473-4, Sept. 15, 2015 (ellipsis in original) (emphasis added).
[1071] *Masters Pharmaceutical, Inc. v. U.S. Drug Enforcement Admin.*, No. 15-1335, 21 (D.C. Cir. 2017).

according to the Acting Administrator, information regarding the scope of drug abuse in a particular area, is also relevant to the question of when a distributor discovers that an order is suspicious, stating:

> [C]onsistent with the ALJ's earlier statement that a violation can be proved "by showing that a suspicious order should have been detected through meaningful due diligence or an effective suspicious order monitoring program," I hold that an order has been discovered to be suspicious and the regulation has been violated where the registrant has obtained information that an order is suspicious but then chooses to ignore that information and fails to report the order. Moreover, a registrant cannot ignore information it obtains that raises a suspicion not only with respect to a specific order, but also as to the legitimacy of a customer's business practices. **Nor, in assessing whether a pharmacy's orders are suspicious can it ignore information it has obtained as to the scope of drug abuse in a particular area.** Certainly, a registrant cannot claim that it has conducted meaningful due diligence or has an effective suspicious order monitoring program when it ignores information it has acquired which raises a substantial question as to the legitimacy of a customer's dispensing practices.[1072]

With respect to the scope of drug abuse in the relevant geographic area at issue in this investigation, and as discussed in section IV(B) of this report, the deleterious impacts of drug abuse, and in particular opioid abuse, have been particularly profound in West Virginia. Between 1999 and 2004, the number of lives lost to accidental drug overdoses in West Virginia increased 550 percent, giving West Virginia the highest unintentional drug overdose death rate in the United States at the time.[1073] According to the Centers for Disease Control and Prevention, in 2017, West Virginia continued to have the highest overdose death rate in the country.[1074]

The Acting Administrator also addressed whether a distributor's obligation to report suspicious orders could be discharged through its own investigation, stating:

> [A] distributor's investigation of the order (coupled with its previous due diligence efforts) may properly lead it to conclude that the order is not suspicious, the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor inform the Agency about the order.[1075]

In its opinion, the D.C. Circuit clarified distributors' obligations to actually investigate individual orders that they chose to ship rather than decline to fill, stating:

[1072] 80 Fed. Reg. 55,478, Sept. 15, 2015 (internal citations omitted) (emphasis added).
[1073] Memorandum from Aron J. Hall, DVM, Epidemic Intelligence Service Officer, W. Va. Dep't of Health & Human Res., et al., to Douglas H. Hamilton, M.D., PhD, Dir., Epidemic Intelligence Service, Centers for Disease Control and Prevention (Oct. 12, 2007) (On file with Committee).
[1074] Centers for Disease Control and Prevention, *Drug Overdose Deaths in the United States, 1999-2017*, NCHS Data Brief (Nov. 2008) *available at* https://www.cdc.gov/nchs/data/databriefs/db329-h.pdf.
[1075] 80 Fed. Reg. 55,418, Sept. 15, 2015 (internal quotations omitted).

> As we have emphasized throughout this opinion, it is not necessary for a distributor of controlled substances to investigate suspicious orders if it reports them to DEA and declines to fill them. But if a distributor chooses to shoulder the burden of dispelling suspicion in the hopes of shipping any it finds to be non-suspicious, and the distributor uses something like [Masters' Suspicious Order Monitoring System] to guide its efforts, then the distributor must actually undertake the investigation.[1076]

The D.C. Circuit agreed with the Acting Administrator that, among other things, such investigations must dispel all red flags that gave rise to the suspicion and that a distributor's investigation must be documented, saying, "the Administrator recognized that, if investigating employees fail to take such basic steps, [the Suspicious Order Monitoring System] does not function as an effective tool for dispelling suspicion."[1077]

As discussed in section VI (A)(1) of this report, in the final order, the Acting Administrator also reiterated a distributor's obligation to conduct due diligence on prospective and existing customers, noting, "the obligation to perform due diligence is ongoing throughout the course of a distributor's relationship with its customer."[1078] In the final order, the Acting Administrator, among other things, referenced that, in certain circumstances, Masters failed to seek further explanation when presented with information that conflicted with what was provided during the due diligence process, leading the Acting Administrator to suggest the company's "purpose in asking these questions was simply to go through the motion of conducting due diligence."[1079]

Through letters sent to all DEA registrants, in-person meetings with distributors, industry conferences, and orders published in the federal register, the DEA has identified and communicated red flags or circumstances that might be indicative of diversion, including, but not limited to:

- One or more physicians are writing a disproportionate share of the prescriptions for controlled substances being filled by a pharmacy; [1080]
- Prescriptions being filled that are written by physicians located a significant distance from a pharmacy;[1081]

[1076] *Masters Pharmaceutical, Inc. v. U.S. Drug Enforcement Admin.*, No. 15-1335, 23-24 (D.C. Cir. 2017).
[1077] *Id.* at 24.
[1078] 80 Fed. Reg. 55,477, Sept. 15, 2015.
[1079] *Id.* at 55,488, fn. 179.
[1080] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Sept. 27, 2006, (On file with Committee); Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Feb. 7, 2007, (On file with Committee).
[1081] *See* 77 Fed. Reg. 62,321, Oct. 12, 2012.

- A pharmacy orders the same controlled substances from multiple distributors;[1082]
- Large quantities of people paying cash for controlled substance prescriptions;[1083]
- A high percentage of the pharmacy's purchases are for controlled substances;[1084]
- A pharmacy orders an excessive amount of a particular controlled substance in comparison to what is purchased by a typical retail pharmacy;[1085] and
- A pharmacy is located in a geographic area that is known to have problem with controlled substance abuse.[1086]

2. Case Studies from the Committee's Investigation

The Committee's investigation revealed that in several instances, distributors continued to supply questionable West Virginia pharmacies with opioids, the volumes of which on their own should have raised red flags, particularly when viewed in context of what should be considered reasonable to support the legitimate medical needs of the local population. In some of these cases, the shipments to the pharmacies were facilitated with very little corresponding due diligence. In other instances, the due diligence materials and other documents collected by the distributors and produced to the Committee should have raised red flags that required distributors to report suspicious orders more frequently and conduct their own independent investigations. The Committee found, however, that distributors continued to ship opioids to these pharmacies for months and, in some cases, even years.

The case studies below will highlight:

- McKesson continued supplying a pharmacy it had previously terminated, and later reinstated, with controlled substances for approximately five months after discovering additional, serious, red flags associated with the pharmacy;

[1082] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Sept. 27, 2006, (On file with Committee); Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Feb. 7, 2007, (On file with Committee).

[1083] *See* 77 Fed. Reg. 62,326, Oct. 12, 2012.

[1084] *See* 72 Fed. Reg. 36,492, July 3, 2007. In this order, the DEA Acting Administrator quoted guidance that had been provided by DEA in which it was stated, "in a typical retail pharmacy, controlled substances might amount to between five and twenty percent of the pharmacy's purchases with the other eighty to ninety percent of its purchases being non-controlled drugs." (internal quotation marks omitted) *See also* 80 Fed. Reg. 55,477, Sept. 15, 2015.

[1085] *See* 72 Fed. Reg. 36,498, July 3, 2007.

[1086] *See* Staff Coordinator, Liaison & Policy Section, Office of Diversion Control, U.S. Drug Enforcement Admin., *Distributor Initiative – A National Perspective*, Oct. 22, 2013, *available at* https://www.deadiversion.usdoj.gov/mtgs/distributor/conf_2013/prevoznik.pdf; *see also* 77 Fed. Reg. 62,322, Oct. 12, 2012 and 80 Fed. Reg. 55,479, Sept. 15, 2015.

- After terminating a pharmacy following a site visit, McKesson did not undertake a review of the pharmacy's other location, which was also a McKesson customer and located approximately three miles away, for nearly sixteen months;

- Over a two-year period, H.D. Smith shipped nearly five million doses of hydrocodone and oxycodone to two pharmacies, located approximately four blocks apart in a town of 3,191. Moreover, H.D. Smith obtained dispensing data which demonstrated that a single doctor was responsible for prescribing more than 158,000 doses of hydrocodone dispensed by one of these pharmacies in February 2008;

- Approximately six months after reporting a pharmacy to the DEA, H.D. Smith was presented with information during a site visit suggesting that 90 to 95 percent of this pharmacy's orders were for controlled substances yet the company continued to ship controlled substances to this pharmacy;

- H.D. Smith determined that a single doctor was writing 51 percent of the hydrocodone prescriptions being filled at a particular pharmacy and did not terminate this pharmacy or restrict its ability to purchase controlled substances, despite terminating another pharmacy approximately three months earlier, in part, because the pharmacy continued to fill prescriptions written by this doctor; and

- Miami-Luken continued to supply controlled substances to a pharmacy, even approving a temporary increase to the pharmacy's oxycodone threshold, after the company determined that it had been lied to by the pharmacy's owner regarding a commitment to stop filling prescriptions written by certain doctors.

a. Case Study on McKesson: Monitoring When Aware of Red Flags

As discussed earlier in this report, McKesson suspended Tug Valley's ability to purchase controlled substances on January 8, 2016, after the pharmacy was prominently featured in a *CBS News* report concerning the role wholesale distributors may have played in exacerbating the opioid epidemic in West Virginia.[1087] In an affidavit submitted after Tug Valley sued McKesson for suspending its ability to purchase controlled substances, a senior director of regulatory affairs at McKesson stated that the company "had a good-faith belief that continued shipments to Tug Valley Pharmacy put McKesson in jeopardy of being noncompliant with federal and/or state laws and regulations concerning the distribution of controlled substances."[1088] The 2016 cessation of McKesson's and Tug Valley's business relationship would be short-lived, however, as the company quickly reinstated Tug Valley as a customer and continued to supply the pharmacy with controlled substances until it cut the pharmacy off again on February 28, 2018, despite discovering serious red flags regarding the pharmacy approximately five months earlier in October 2017.

[1087] *See supra* Section VI(A)(2)(c)(i)

[1088] *Tug Valley Pharmacy v. McKesson Corporation* No. 16-C-64 (Kanawha County, W.Va. Circuit Court) (Jan. 25, 2016) (Affidavit of [Senior Director of Regulatory Affairs, McKesson Corp.]) (On file with Committee) (internal quotation marks omitted).

On February 26, 2016, the month following the pharmacy's appearance on the *CBS News*, McKesson reinstated Tug Valley as a customer after the pharmacy was purchased by another individual.[1089] Given the allegations against the previous owner, Tug Valley's new owner represented to McKesson that the previous owner no longer had any association with the pharmacy.[1090] This representation appears to have been critical to McKesson's decision to reinstate Tug Valley.

Notwithstanding documents provided by the pharmacy to McKesson indicating that the previous owner provided the financing arrangement to facilitate the sale of the pharmacy while also retaining a security interest in the pharmacy,[1091] McKesson appears to have relied on the statement from the new owner that the previous owner no longer had any association with the pharmacy. However, twenty months later, in October 2017, McKesson learned that the previous owner was, in fact, working at the pharmacy.[1092]

Documents produced to the Committee indicate McKesson conducted due diligence at various points between February 2016 and October 2017 that did not yield evidence that the former owner had any direct association with the pharmacy during this time, meaning that McKesson could not tell from the face of the documents provided by the pharmacy that the previous owner was still involved. For example, the former owner was not listed among the pharmacy's employees on a September 2017 threshold change request form despite the fact that the new owner said he returned to the pharmacy in June 2017.[1093] This suggests that the new owner may have taken deliberate action to conceal the former owner's involvement from McKesson. McKesson, however, does not appear to have attempted to independently confirm that the previous owner was no longer associated with the pharmacy, such as by directly asking the pharmacy or conducting a site visit whereby McKesson could interview pharmacy employees.

McKesson appears to have realized that the previous owner was still associated with the pharmacy somewhat by happenstance. On October 3, 2017, when it was conducting due diligence on Tug Valley's request to increase its buprenorphine threshold, a McKesson investigator called the pharmacy and the previous owner answered the phone.[1094] A Regulatory

---

[1089] McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy II, Feb. 29, 2016 (On file with Committee). As discussed earlier, the circumstances attendant to the transfer of ownership and McKesson's ultimate decision to reinstate the pharmacy are highly questionable. *See supra* Section VI(A)(2)(c).

[1090] McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy II, Feb. 29, 2016 (On file with Committee).

[1091] *See* McKesson Corp., Due Diligence Document – Tug Valley Pharmacy – Promissory Note and Guaranty Agreement, Feb.11, 2016 (On file with Committee); McKesson Corp., Due Diligence Document – Tug Valley Pharmacy – Security Agreement, Feb.11, 2016 (On file with Committee); McKesson Corp., Due Diligence Document – Tug Valley Pharmacy – Agreement, Feb. 11, 2016 (On file with Committee).

[1092] *See* McKesson Corp., Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, Oct. 11, 2017 (On file with Committee).

[1093] *See* McKesson Corp., Threshold Change Request Form – Tug Valley Pharmacy, Sept. 27, 2017 (On file with Committee).

[1094] *See* McKesson Corp., Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, Oct. 11, 2017 (On file with Committee).

Investigative Report, authored eight days later documented this phone call.[1095] The report also noted, "[the former owner's] name does not appear on the [Threshold Change Request (TCR)] form or the McKesson [Controlled Substances Monitoring Program] questionnaire that was included in the TCR package."[1096] The report also referenced McKesson's decision to suspend Tug Valley's ability to purchase controlled substances during the former owner's tenure as well as the pharmacy being featured on the *CBS News* in relation to the lawsuit concerning its prescribing practices under the former owner.[1097] The portion of the McKesson report that references the litigation and McKesson's previous decision to suspend the pharmacy is reproduced below:

> During an open Internet search, including the OIG Exclusion website, derogatory information was found concerning [redacted] The derogatory information references Tug Valley Pharmacy, under the ownership of [redacted] and Tug Valley Pharmacy are mentioned in a civil action (no. 10-c-251) and a circuit court order (no. 14-0144). A CBS News article noted that Tug Valley Pharmacy was being sued for negligently filling prescriptions. (See links below.)
> http://www.courtswv.gov/supreme-court/calendar/2015/briefs/march15/14-0144order.pdf
> http://www.courtswv.gov/supreme-court/calendar/2015/briefs/march15/14-0144respondent.pdf
> http://www.cbsnews.com/news/drug-distributors-under-fire-in-west-virginia-painkiller-epidemic/
>
> It is noted that McKesson suspended Tug Valley Pharmacy's, under the ownership of [redacted] ability to purchase controlled substances on January 8, 2016.

In addition to documenting McKesson's discovery that the former owner continued to have an affiliation with the pharmacy, the report also noted that the Kentucky State Board of Pharmacy took action against another pharmacist employed by Tug Valley for filling fraudulent hydrocodone prescriptions.[1098] According to the report, McKesson determined that the pharmacist had pleaded guilty to a felony charge and that the pharmacy needed a waiver from the DEA if he were to remain employed by the pharmacy.[1099] Pursuant to the Regulatory Investigative Report, McKesson denied Tug Valley's request to increase its buprenorphine threshold.[1100]

McKesson drafted a second Regulatory Investigative Report two days later regarding the discoveries made by the company when it was evaluating Tug Valley's threshold request.[1101] This report referenced the findings from the earlier report, stating, "two current staff pharmacists have pending or finalized litigation or disciplinary actions which needed clarification to

---

[1095] *Id.*
[1096] *Id.*
[1097] *Id.*
[1098] *See Id.*
[1099] *Id.* DEA regulations prohibit registrants from employing individuals who have access to controlled substances and have been convicted of a felony related to controlled substances unless a waiver is obtained from the DEA. *See* 21 CFR §1301.76(a) and 56 Fed. Reg. 36,727 (Aug. 1, 1991).

[1101] *See* McKesson Corp., Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, Oct. 13, 2017 (On file with Committee).

effectively assess JCL Management & Consulting, LLC., dba: Tug Valley Pharmacy's status as a McKesson customer."[1102] With respect to the former owner of Tug Valley Pharmacy, the report stated:

> On October 3, 2017, [the Regulatory Affairs Manager] contacted the pharmacy to inquire about prescribing physicians listed as part of the TCR. She spoke with [Tug Valley's former owner], a relief pharmacist at JCL Management & Consulting, LLC., dba: Tug Valley Pharmacy. [The Regulatory Affairs Manager] recognized that [the former owner] was the former owner of Tug Valley Pharmacy, a customer terminated by McKesson Regulatory Affairs on January 8, 2016. This termination was based on pending civil litigation against [the former owner] which alleged that [the former owner] neglected his pharmacist's corresponding responsibilities when filling prescriptions for controlled substances. Following the termination of this account, [the former owner] sold Tug Valley Pharmacy to [the new owner]. Pursuant to McKesson's Change of Ownership procedures, [the new owner's] ownership was approved and the pharmacy became a McKesson customer on February 26, 2016. When on-boarded, it was believed by McKesson Regulatory Affairs personnel that [the former owner] had relinquished any connection to Tug Valley Pharmacy, including employment opportunities.[1103]

McKesson's Director of Regulatory Affairs spoke with Tug Valley's new owner regarding the employment of the former owner as well as the pharmacist with a felony conviction related to controlled substance diversion. With respect to the conversation related to Tug Valley's employment of its former owner, the report stated:

> [The Director of Regulatory Affairs] asked [Tug Valley's new owner] about [Tug Valley's former owner's] employment at the pharmacy. [The Director of Regulatory Affairs] prefaced the question by stating that it was McKesson's understanding that when the change of ownership at Tug Valley was approved, [the former owner] would have no affiliation with the pharmacy. [The new owner] stated that when the ownership of the pharmacy transferred to him, [the former owner] had no affiliation with the pharmacy, including employment opportunities. [The new owner] said this status changed in June 2017 when one of the pharmacy's staff pharmacists passed away. [The new owner] stated that he needed to find a pharmacist to fill in occasionally for regular staff. [The new owner] added that because of the pharmacy's rural location it is not easy finding reliable pharmacist's [sic] help. Because of these staffing issues, he asked [the former owner] to

---

[1102] *Id.*

[1103] *Id.* McKesson's stated belief that the former owner "relinquished any connection to Tug Valley Pharmacy," seems to conflict with McKesson's knowledge that, pursuant to documents provided to McKesson in February 2016, the former owner retained a security interest in the pharmacy at the time McKesson reinstated Tug Valley as a customer. The circumstances surrounding the sale of Tug Valley Pharmacy in February 2016 are discussed in greater detail in section VI(A)(2)(c)(ii).

> fill in until he could find a permanent pharmacist replacement. [The new owner] added that he hired [the former owner] to work part-time hours working approximately 10 – 20 hours weekly at the pharmacy. [The new owner] added that [the former owner] would be excused from this part-time position once a permanent replacement was found.

The report also notes that McKesson's Director of Regulatory Affairs told Tug Valley's new owner that if the pharmacy did not find a replacement for the former owner by October 31, 2017, it would suspend Tug Valley's ability to purchase controlled substances.[1104] The report stated:

> [The Director of Regulatory Affairs] reiterated McKesson's concerns about [the former owner's] employment because of on-going civil litigation with [the former owner]. [The Director of Regulatory Affairs] told [the new owner] that McKesson could not tell [the new owner] whom to employ, but the company had issues with [the former owner] due to the pending civil litigation. [The Director of Regulatory Affairs] told [the new owner] that McKesson would allow [the new owner] until October 31, 2107 [sic] to find a replacement for [the former owner]. If [the new owner] did not find a replacement for him by October 31, 2017, McKesson would "suspend" JCL Management & consulting, LLC., dba: Tug Valley Pharmacy's ability to order controlled substances. [The new owner] said that he would need more time due to the problems in finding reliable help.[1105]
>
> Later the same day, the Director of Regulatory of Affairs spoke with Tug Valley Pharmacy's new owner again, this time, to discuss the need for the pharmacy to obtain a waiver from the DEA related to its employment of a pharmacist with a controlled substance-related felony conviction.[1106] According to the report, the new owner told McKesson that the pharmacist would not work at the pharmacy until the DEA waiver was obtained.[1107]

The report concluded, "McKesson's Regulatory Affairs will monitor the status of current pharmacy staff until October 31, 2017. On this date, if [Tug Valley's new owner] has not found adequate staffing resources, the pharmacy's ability to order controlled substances will be suspended."[1108]

[1104] *Id.*
[1105] *Id.*
[1106] *Id.*
[1107] *Id.*
[1108] *Id.*

FINDING: **When McKesson reinstated Tug Valley Pharmacy as a customer in February 2016, the pharmacy's new owner assured McKesson that its former owner no longer had any association with the pharmacy. However, after learning in October 2017 the former owner was employed by the pharmacy, as was a pharmacist with a felony conviction related to controlled substances, McKesson did not terminate or restrict Tug Valley's ability to purchase controlled substances.**

A November 1, 2017, Regulatory Investigative Report indicates that McKesson did follow-up with Tug Valley regarding the employment status of the former owner as well as that of the pharmacist with the controlled substance-related felony conviction.[1109] With respect to the former owner, Tug Valley's new owner told McKesson's Director of Regulatory Affairs that "he found another pharmacist to replace [the former owner]; however, that pharmacist could not begin working until November 7, 2017."[1110] The report also documented a conversation the Director of Regulatory Affairs had with the new owner regarding the pharmacist with the controlled-substance felony conviction, noting:

> [The new owner] stated that [the pharmacist] was not employed as a pharmacist at the store. [The new owner] added that he had submitted the paperwork required for the waiver consideration to DEA, despite being told by them that [the pharmacist] could continue his employment while the waiver was being reviewed. [The new owner] reiterated that [the individual] would not work at JCL Management & Consulting, LLC dba: Tug Valley Pharmacy until a decision on the waiver was rendered.[1111]

Based upon the representations made by the new owner, the Director of Regulatory Affairs recommended that Tug Valley remain a McKesson customer.[1112] Documents provided to the Committee show no attempt by McKesson to verify the representations made by Tug Valley regarding the employment status of either individual, such as by contacting the pharmacy again after November 7, 2017 to confirm that the new pharmacist hired to replace the former owner had begun work. In fact, McKesson told the Committee that it did not make any additional inquiries with respect to either individual until February 28, 2018.[1113]

[1109] *See* McKesson Corp., Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, Nov. 1, 2017 (On file with Committee).
[1110] *Id.*
[1111] *Id.*
[1112] *See Id.*
[1113] *See* E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).

FINDING: During a November 1, 2017 conversation between McKesson's Director of Regulatory Affairs and Tug Valley's new owner, the pharmacy owner made representations about the former owner and the convicted pharmacist that McKesson did not attempt to verify until February 28, 2018.

McKesson finally suspended Tug Valley Pharmacy's ability to purchase controlled substances on February 28, 2018, the same day McKesson conducted a site visit to the pharmacy and discovered that the individual with a controlled substance-related felony conviction continued to be employed as a pharmacist at Tug Valley despite not receiving the necessary DEA waiver, and in direct contradiction to the new owner's pledge that the individual would not be employed by the pharmacy until such a waiver was obtained.[1114]

According to a Regulatory Investigative Report which documented the site visit, the individual was listed among Tug Valley's pharmacists and worked "on an 'as needed' basis[.]"[1115] During the site visit, the Regulatory Affairs Manager also inquired about the employment status of Tug Valley's former owner and was told by Tug Valley's Pharmacist in Charge that the former owner no longer worked at the pharmacy, adding that he was unable to recall the last time the former owner worked at the pharmacy.[1116]

On the same day as the site visit, McKesson's Director of Regulatory Affairs addressed the pharmacy's continued employment of the individual with a controlled substance-related felony conviction during a conversation with Tug Valley's new owner. This conversation is documented in a separate Regulatory Investigative Report, which stated:

> To gain further insight into [the pharmacist's] employment, [the Director of Regulatory Affairs] spoke with [the new owner] on February 28, 2018. [The Director of Regulatory Affairs] asked [the new owner] if [the pharmacist] had recently worked at Tug Valley Pharmacy as a pharmacist. [The new owner] stated that [the pharmacist] had worked on one occasion because of scheduling conflicts. [The Director of Regulatory Affairs] asked [the new owner] if the employment waiver from DEA had been finalized allowing [the pharmacist's] employment. [The new owner] said the waiver had been submitted but no official word had been received. [The new owner] said it could take months before a decision was made.
>
> [The Director of Regulatory Affairs] asked about their previous conversation when [the new owner] committed to not further employ [the pharmacist] until the waiver had been granted. [The new owner] argued with [the Director of Regulatory Affairs] by saying that finding pharmacist

[1114] McKesson Corp., Dir. Regulatory Affairs, Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, Apr. 11, 2018 (On file with Committee).
[1115] McKesson Corp., Regulatory Affairs Manager, Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, Apr. 11, 2018 (On file with Committee).
[1116] *Id.*

> staff was difficult in this area of West Virginia and, besides that, the DEA told [the new owner] that [the pharmacist] could work while the waiver was being processed. [The Director of Regulatory Affairs] reiterated that a pharmacist could not work until the waiver was granted and asked [the new owner] for the name of the DEA employee who gave that information to him. [The new owner] could not recall any name or contact information regarding the DEA employee.[1117]

McKesson's ultimate realization of the individual's continued employment at Tug Valley Pharmacy does not appear to have been a product of its own follow-up. As indicated below, two Regulatory Investigative Reports state that McKesson initiated the February 2018 review after the company received an inquiry from a pharmaceutical manufacturer related to Tug Valley pharmacy.[1118]

> Pursuant to a manufacturer inquiry from [redacted], RAM [redacted] conducted a triggered event review at JCL Management and Consulting, dba: Tug Valley Pharmacy; hereinafter Tug Valley Pharmacy on February 28, 2018. [redacted]

> On February 20, 2018, Senior Director of Regulatory Affairs [redacted] informed the Washington Court House Regulatory Affairs team of [redacted]'s due diligence request. Tug Valley Pharmacy was identified by [redacted]. Senior Director of Regulatory Affairs [redacted] requested an event-triggered due diligence review of the pharmacy.

While McKesson's ultimate decision to restrict the pharmacy's ability to purchase controlled substances is commendable, this action came nearly five months after the company discovered serious red flags with a pharmacy that it terminated in the past for compliance reasons. Moreover, the October 2017 report that began this process came twenty months after McKesson reinstated the pharmacy as a customer almost immediately after terminating it for compliance reasons. Only after receiving a third-party inquiry regarding Tug Valley, did McKesson conduct a site visit in February 2018.

FINDING: McKesson's February 28, 2018 site visit to Tug Valley, which resulted in the pharmacy's termination, was initiated by a third-party request, not McKesson's own proactive due diligence.

At the time it terminated Tug Valley's ability to purchase controlled substances in February 2018, McKesson was also supplying controlled substances to three other pharmacies

---

[1117] *See* McKesson Corp., Dir. Regulatory Affairs, Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, Apr. 11, 2018 (On file with Committee).

[1118] *See* McKesson Corp., Dir. Regulatory Affairs, Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, Apr. 11, 2018 (On file with Committee). *See also* McKesson Corp., Regulatory Affairs Manager, Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, Apr. 11, 2018 (On file with Committee).

owned by Tug Valley's new owner, including the former Sav-Rite No. 1 which was operating under a different name.[1119] Given the repeated misrepresentations made by the new owner and the company's decision to terminate Tug Valley's ability to purchase controlled substances, the Committee asked McKesson whether it terminated its relationship with or restricted the owner's other pharmacies from purchasing controlled substances.[1120] In response to the Committee's question, McKesson indicated that it had not, adding, "[d]ue diligence reviews conducted on the other three pharmacies and their employees have not revealed any areas of concern."[1121] It is not clear, however, when such due diligence reviews occurred or whether they took the owner's misrepresentations to McKesson, involving individuals linked to controlled substance diversion, into account had any such reviews occurred following the company's decision to terminate Tug Valley.

As mentioned, in a 2015 final order revoking the registration of another wholesale distributor, DEA's then-Acting Administrator noted that "a pharmacy's business model, dispensing patterns, or other characteristics" may all be factors that a distributor should take into account when assessing whether a controlled substances order placed by a pharmacy is suspicious.[1122] Given the multiple, documented, misrepresentations made by the new owner of Tug Valley Pharmacy, a pharmacy which was purchased under questionable circumstances, in a region of West Virginia that has been severely impacted by the opioid epidemic, McKesson should be particularly vigilant when evaluating controlled substance orders placed by the new owner's other pharmacies.

b. *Case Study on McKesson: Evaluation of an Owner(s)'s Other Pharmacies*

As previously discussed in this report, McKesson supplied hydrocodone and oxycodone to Family Discount Pharmacy in Mount Gay-Shamrock, West Virginia, population 1,779,[1123] at various times between 2006 and 2014.[1124] In that time, the pharmacy received more than 5.91 million doses of opioids from McKesson alone, making it McKesson's top purchaser of hydrocodone and oxycodone in West Virginia.[1125] McKesson also supplied Family Discount

---

[1119] *See* E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee); *see also* Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee). As discussed in greater detail in section VI(A)(2)(c)(ii), the circumstances surrounding the new owner's February 2016 acquisition of Tug Valley Pharmacy are highly questionable. Documents produced to the Committee and the Committee's own research indicates that Tug Valley's new owner acquired the other three pharmacies at approximately the same time, during or around April 2017. *See* McKesson Corp., ISMC Customer Questionnaire – Tug Valley Pharmacy, Apr. 26, 2017 (On file with Committee).

[1120] *See* E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (July 31, 2018 11:10 am) (On file with Committee).

[1121] E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).

[1122] *See* 80 Fed. Reg. 55,4734, Sept. 15, 2015.

[1123] American FactFinder, *Mount Gay-Shamrock (CDP), West Virginia* (https://factfinder.census.gov).

[1124] *See supra* Section VI(A)(2)(b).

[1125] McKesson Corp., Ten Largest West Virginia Hydrocodone and Oxycodone – 2006 – 2017 (On file with Committee). As discussed in greater detail in Section VI(A)(2)(b), McKesson told the Committee that Family

Pharmacy's second location in Stollings, West Virginia, population 316,[1126] with more than 2.37 million doses of hydrocodone and oxycodone at various times between 2006 and 2015.[1127] Combined, McKesson supplied more than 8.29 million doses of opioids to these two pharmacies, located just three miles apart. As will be discussed below, even after terminating Family Discount Pharmacy in Mount Gay-Shamrock in April 2014 due to red flags related to the pharmacy's dispensing practices, McKesson continued to distribute opioids to Family Discount Pharmacy in Stollings and failed to conduct any due diligence on the pharmacy for nearly sixteen months.

FINDING: At various times during a ten-year period, McKesson shipped more than 8.29 million doses of opioids to two commonly owned pharmacies, located just three miles apart in rural West Virginia.

i. McKesson's 2014 Termination of Family Discount Pharmacy in Mount Gay-Shamrock

On March 27, 2014, McKesson conducted a site visit to Family Discount Pharmacy in Mount Gay-Shamrock, West Virginia, to follow up on the pharmacy's request to increase its monthly threshold for alprazolam.[1128] According to a report authored by McKesson's Director of Regulatory Affairs, at the time of the site visit, Family Discount Pharmacy had purchased more than half a million dosage units of alprazolam over the past year.[1129] The pharmacy's alprazolam purchase history between April 2013 and March 2014 was included in the report, and reproduced in relevant part below:

Discount Pharmacy's Mount Gay-Shamrock location was included on a list of pharmacies McKesson terminated for compliance reasons and e-mailed to the DEA on February 6, 2009. *See* Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee). In 2010, Family Discount Pharmacy's Mount Gay-Shamrock location once again became a McKesson customer. This engagement was short-lived, however, as McKesson told the Committee, "McKesson records indicate that Family Discount Pharmacy (Mount Gay-Shamrock)'s first controlled substances order in 2010 was on March 2, and its last controlled substances order in 2010 was on March 26. Currently available records do not make clear why McKesson discontinued supplying controlled substances to the pharmacy in 2010." E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 12, 2018 4:22 pm) (On file with Committee). Thereafter, Family Discount Pharmacy's Mount Gay-Shamrock location resumed its relationship with McKesson in September 2012.

[1126] American FactFinder, *Stollings (CDP), West Virginia* (https://factfinder.census.gov).

[1127] U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee).

[1128] Alprazolam is a type of benzodiazepine, a sedative commonly involved in opioid overdoes. In 2016, the Food and Drug Administration mandated that 'black box' warnings be added to opioid and benzodiazepine packaging, warning of the dangers that could result from taking both types of medication simultaneously. *See* Nat'l Inst. on Drug Abuse, *Benzodiazepines and Opioids* (last updated Mar. 2018) *available at* https://www.drugabuse.gov/drugs-abuse/opioids/benzodiazepines-opioids; *see also* Press Release, U.S. Food and Drug Admin., FDA requires strong warnings for opioid analgesics, prescription opioid cough products, and benzodiazepine labeling related to serious risks and death from coming use (Aug. 31, 2016), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm518697.htm.

[1129] McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Mount Gay-Shamrock), May 2, 2014 (On file with Committee).

PURCHASE HISTORY REVIEW

A purchase history review indicated from April 2013 through March 2014, Family Discount Pharmacy ordered 561,320 dosage units of Alprazolam. See chart below:

APR 2013	65,000	65	62,620
MAY 2013	65,000	48	47,500
JUN 2013	65,000	59	57,600
JUL 2013	65,000	52	51,500
AUG 2013	65,000	58	52,880
SEP 2013	65,000	65	63,600
OCT 2013	19,000	64	60,720
NOV 2013	19,000	19	19,000
DEC 2013	36,930	42	36,920
JAN 2014	36,930	45	36,800
FEB 2014	36,930	42	36,480
MAR 2014	36,930	38	35,700
Total	36,930	597	561,320

The report also indicated that Family Discount was receiving hydrocodone in addition to what was supplied by McKesson, and that the pharmacy purchased nearly five times the amount of hydrocodone than a nearby Rite Aid Pharmacy, which was also a McKesson customer.[1130] With respect to Family Discount Pharmacy's purchases of hydrocodone, the report stated, "[i]n particular, the hydrocodone dispensing data indicates that Family Discount Pharmacy purchases more hydrocodone than McKesson supplied (70,000 doses monthly versus 81,367 doses dispensed for four month period of December 2013 through March 27, 201[4])."[1131] The report continued, "[o]ther information obtained during this investigation revealed that another McKesson customer, Rite Aid Pharmacy, located in the same area as Family Discount Pharmacy, only purchased approximately 15,000 doses of hydrocodone monthly."[1132] During an earlier site visit, McKesson also observed that there were several national retail chain pharmacies within a ten-mile radius of Family Discount Pharmacy.[1133]

During the March 27, 2014, site visit, the pharmacy's owner told the McKesson investigator, "he utilizes McKesson as his primary distributor but uses Miami-Luken in Ohio as a secondary distributor. No other distributor has ever restricted or ceased controlled substances sales from any pharmacy [the owner] has owned or been employed."[1134] As discussed earlier in section VI(A)(2)(b)(ii) of this report, however, McKesson told the Committee that it informed

[1130] *Id.*
[1131] *Id.*
[1132] *Id.*
[1133] McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Mount Gay-Shamrock), Mar. 24, 2014 (On file with Committee).
[1134] McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Mount Gay-Shamrock), May 2, 2014 (On file with Committee).

the DEA in a 2009 e-mail that it terminated Family Discount Pharmacy as a customer "for compliance reasons."[1135]

A week after the March site visit, the Director of Regulatory Affairs spoke to a local law enforcement officer who said that the county where Family Discount was located had "serious prescription drug abuse issues."[1136] The officer also alerted McKesson to area doctors that provided cause for concern, including two whose "controlled substances prescriptions are frequently dispensed at Family Discount Pharmacy."[1137] McKesson noted that the Rite Aid had ceased filling prescriptions written by two area doctors, one of whom had been identified by the law enforcement officer, due to questionable prescribing patterns, but Family Discount had not.[1138]

FINDING: Family Discount Pharmacy in Mount Gay-Shamrock purchased nearly five times the amount of hydrocodone from McKesson than a nearby Rite Aid Pharmacy. McKesson fulfilled the orders placed by Family Discount Pharmacy during a time when the surrounding area had "serious prescription drug abuse issues" per a local law enforcement officer.

Following the site visit and discussion with local law enforcement, the company discontinued selling controlled substances to Family Discount Pharmacy on April 8, 2014.[1139] This decision was documented by McKesson in a subsequent Regulatory Investigative Report and is reproduced in relevant part below:

CONCLUSION/RECOMMENDATION

On April 8, 2014, DRA [redacted] via SAP reduced this customer's controlled substance to zero and entered "ineligible" coding for future sales.

Documents produced to the Committee indicate the pharmacy continued to attempt to order controlled substances from McKesson, even after its ability to do so had been terminated by the company. For example, out of the 138 total orders placed by Family Discount Pharmacy that McKesson reported to the DEA as suspicious, 36 were placed after April 8, 2014, with latest order being October 19, 2015.[1140] The documents produced to the Committee give no indication

[1135] *See supra* Section VI(A)(2)(b)(ii); *see also* Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).
[1136] McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Mount Gay-Shamrock), May 2, 2014 (On file with Committee).
[1137] *Id.*
[1138] *Id.*
[1139] McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Mount Gay-Shamrock), Apr. 11, 2014 (On file with Committee).
[1140] McKesson Corp., West Virginia Suspicious Orders Reported to the DEA 2013 – 2017 (On file with Committee).

why the pharmacy continued to place orders for controlled substances after its ability to do so was terminated on April 8, 2014, or whether any orders placed after this date were filled.

ii. McKesson's Distribution to Family Discount Pharmacy-Stollings

McKesson also supplied controlled substances to Family Discount Pharmacy's secondary location in Stollings, West Virginia, located just three miles from the Mount Gay-Shamrock store. The common ownership between the two pharmacies emerged multiple times in documents produced by McKesson. For example, a January 2010 questionnaire regarding the Mount Gay-Shamrock location mentions the Stollings location, as does an August 2012 questionnaire.[1141] During the March 27, 2014 site visit to the Mount Gay-Shamrock location, the pharmacy's owner again disclosed that he was also a co-owner of the Stollings location.[1142] Despite McKesson's decision in April 2014 to terminate Family Discount Pharmacy in Mount Gay-Shamrock, the company continued to supply the Stollings location with opioids.

Documents initially produced to the Committee indicated that McKesson did not perform a review of the Stollings pharmacy until August 2015—sixteen months after McKesson terminated the Mount Gay-Shamrock location. The Committee accordingly asked McKesson to confirm whether it performed a site visit or conducted supplemental due diligence on the Stollings pharmacy between the April 2014 termination of the Mount Gay-Shamrock location, and the August 2015 review.[1143] In response, McKesson told the Committee:

> Yes, McKesson did conduct a review of the Stollings pharmacy around the time of its decision to terminate access to controls with the Mt. Gay pharmacy. [McKesson's Senior Director of Regulatory Affairs and Regional Director of Regulatory Affairs] reviewed purchase data associated with both pharmacies and concluded from their review that purchasing levels from the Stollings pharmacy were measurably different from the Mt. Gay pharmacy. Attached are handwritten notes from [McKesson's Senior Director of Regulatory Affairs] which McKesson was able to locate documenting the assessment of both Family Discount Pharmacy locations at the time. McKesson also conducted an on-site regulatory review of the Stollings pharmacy in August 2015.[1144]

McKesson further told the Committee, "[t]he review referenced was not an on-site review. The review was conducted at approximately the same time as the decision to terminate the Mount Gay-Shamrock location's access to controlled substances, but the exact date is not

---

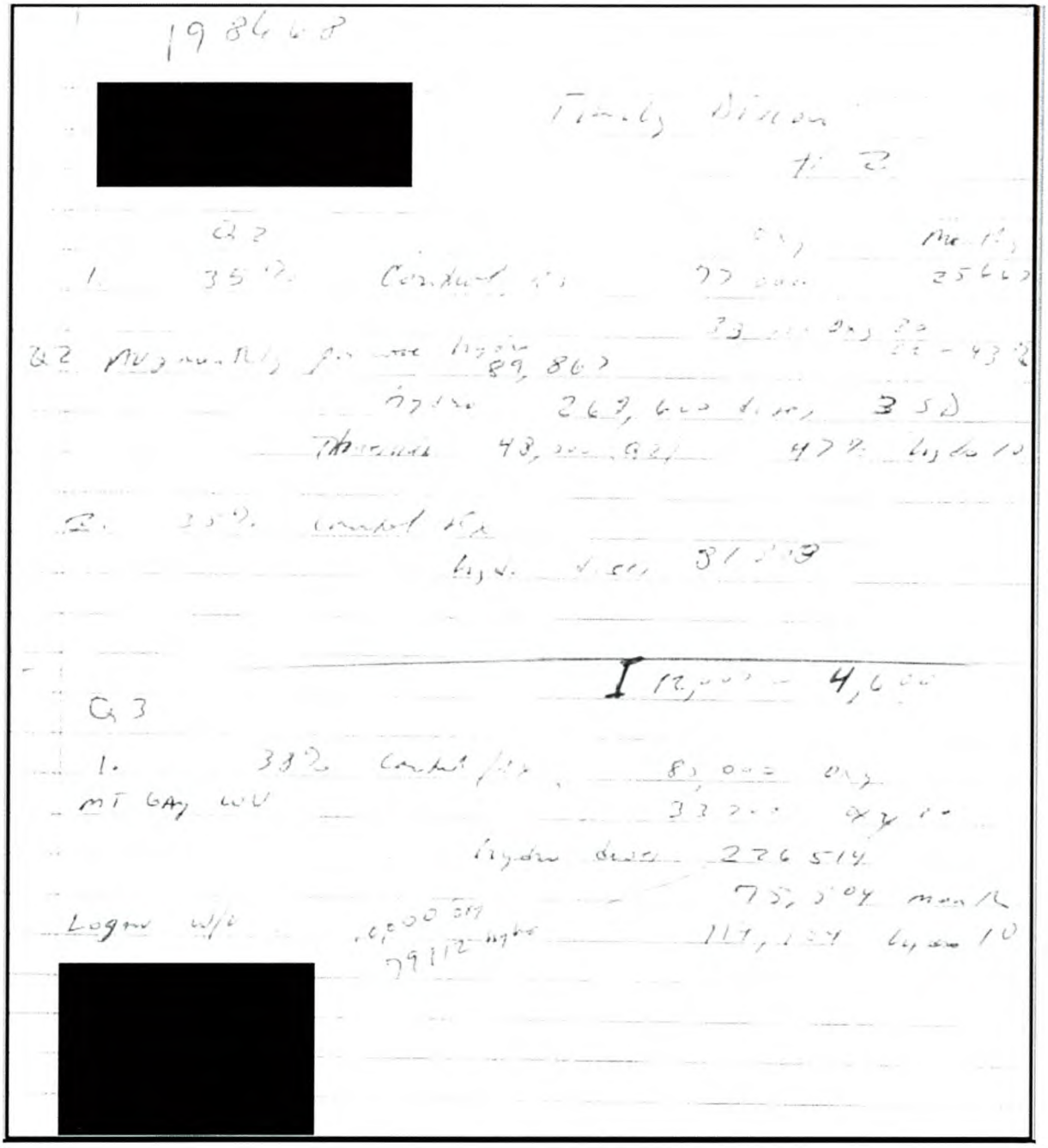
[1141] *See* McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy (Mount Gay-Shamrock), Jan. 26, 2010 (On file with Committee); *see also* McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy (Mount Gay-Shamrock), Aug. 24, 2012 (On file with Committee).

[1142] McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Mount Gay-Shamrock), May 2, 2014 (On file with Committee).

[1143] *See* E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (July 31, 2018 11:10 am) (On file with Committee).

[1144] E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).

known."[1145] The notes documenting McKesson's review of both Family Discount Pharmacy locations, and referenced in the company's response to the Committee, were a single page which is reproduced in its entirety below.[1146]



[1145] E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 12, 2018 4:22 pm) (On file with Committee).
[1146] McKesson Corp., Due Diligence Notes – Family Discount Pharmacies (Mount Gay-Shamrock and Stollings) (On file with Committee).

Aside from these notes, which McKesson told the Committee "are the only available record of which McKesson is currently aware[,]"[1147] McKesson has not produced any other documents that demonstrate analysis or review of the Stollings location following McKesson's April 2014 termination of the Mount Gay-Shamrock location and prior to August 2015. McKesson's response to the Committee indicates the company did not conduct additional due diligence on the Stollings location for sixteen months after it terminated the Mount Gay-Shamrock location in April 2014.

FINDING:	**McKesson terminated Family Discount's Mount Gay-Shamrock pharmacy in April 2014, but did not undertake an on-site regulatory review of the co-owned Stollings location until sixteen months later. McKesson did review purchase data from the Stollings pharmacy around the time it terminated the Mount Gay-Shamrock location, however, documentation produced to the Committee regarding that review consisted of only a single page of handwritten notes.**

McKesson performed a proactive on-site regulatory review of the Stollings location on August 6, 2015.[1148] With respect to this review, McKesson told the Committee, "[t]he review conducted by McKesson's regulatory affairs team revealed no issues with the Family Discount Pharmacy of Stollings."[1149]

Given McKesson's prior termination of the Mount Gay-Shamrock location, which had common ownership with the Stollings pharmacy, certain disclosures made by the pharmacy during the August 2015 review should have been a source of concern for McKesson. For example, in the CSMP questionnaire dated the same day as the site visit, the pharmacy did not answer the question regarding whether any other pharmacy that was owned or is owned by any of the pharmacy's owners had its ability to purchase controlled substances restricted or terminated in the past ten years.[1150] This portion of the August 6, 2015 CSMP questionnaire is reproduced below:

[1147] E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 12, 2018 4:22 pm) (On file with Committee).

[1148] *See* McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Stollings), Oct. 8, 2015 (On file with Committee).

[1149] Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).

[1150] McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy (Stollings), Aug. 6, 2015 (On file with Committee).

x. Has any previous wholesaler / manufacturer ceased shipping or restricted purchases of controlled substances to a pharmacy that was owned or is owned by current owner/s during the past ten years?

☐Yes ☐No

Explanation:

The documents produced to the Committee give no indication that McKesson questioned Family Discount about this omission, and the report summarizing the site visit made no mention of the action the company took against the pharmacy's Mount Gay-Shamrock location for compliance concerns, or the pharmacy's continued attempts to order controlled substances from McKesson despite having its ability to do so terminated by the company.[1151] In addition, the report noted that during the August 2015 site visit, the pharmacy provided McKesson with the names of two doctors who had oxycodone prescriptions filled at the Stollings location[1152]—one of whom McKesson referenced in the report detailing the company's reasoning for terminating the Mount Gay-Shamrock location, after the doctor was identified by local police as being a cause for concern.[1153]

The report also made no reference to suspicious orders related to the Stollings location that McKesson reported to the DEA. From the time it began reporting suspicious orders to the DEA in August 2013, McKesson reported 85 suspicious orders placed by the Stollings location, 49 of which came after McKesson discontinued selling controlled substances to the pharmacy's Mount Gay-Shamrock location.[1154] By the time of the August 2015 site visit, McKesson had reported 82 suspicious orders to the DEA about the Family Discount Pharmacy in Stollings.[1155]

Despite the significant number of suspicious orders originating from the Stollings pharmacy, warnings about drug abuse issues in the community, and the common ownership with a nearby pharmacy McKesson terminated for concerning dispensing practices, McKesson continued to supply the Stollings location with controlled substances. It was not until the pharmacy elected to discontinue its business relationship with McKesson in early 2016 that McKesson stopped supplying controlled substances to the Stollings location.[1156]

[1151] *See* McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Stollings), Oct. 8, 2015 (On file with Committee

[1152] *See Id.*

[1153] *See* McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Mount Gay-Shamrock), May 2, 2014 (On file with Committee).

[1154] McKesson Corp., West Virginia Suspicious Orders Reported to the DEA 2013 – 2017 (On file with Committee). In total, McKesson submitted 223 suspicious order repots to the DEA for orders placed by both Family Discount locations.

[1155] *Id.*

[1156] *See* Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).

Had McKesson undertaken a proactive review of the Stollings location in a timelier manner, and incorporated the findings which prompted the company to terminate the Mount Gay-Shamrock location's ability to purchase controlled substances into any such review, it would have been better positioned to identify and mitigate any potential red flags of diversion associated with the Stollings location.

c. *Case Study on H.D. Smith: Common Diversion Concerns Involving Pharmacies in the Same Geographic Area*

Between 2007 and 2008, H.D Smith provided Hurley Drug Company in Williamson, West Virginia, with more than 2.88 million doses of hydrocodone and oxycodone.[1157] In the same time period, H.D. Smith provided Tug Valley Pharmacy, also located in Williamson, with more than 2.1 million doses of hydrocodone and oxycodone.[1158] Hurley Drug Company and Tug Valley Pharmacy are located approximately four blocks apart from each other in Williamson, which had a population of 3,191 in 2010.[1159] In total, H.D. Smith provided these two pharmacies with nearly five million doses of hydrocodone and oxycodone in just two years.[1160]

H.D. Smith's analysis of dispensing data produced by these pharmacies provided the company with concern, however, prompting it to alert the DEA in April 2008. Despite this action, the company continued to supply Tug Valley with controlled substances until August 2009, and continued to supply Hurley Drug Company until September 2011. In total, H.D. Smith supplied both pharmacies with more than 6.82 million doses of hydrocodone and oxycodone between 2007 and 2011.[1161]

H.D. Smith told the Committee that it requested dispensing and prescribing data from pharmacy customers in situations when the company deemed that further investigation of a particular customer was necessary.[1162] Specifically, H.D. Smith told the Committee:

> Dispensing and prescribing data provides greater insight to H.D. Smith into the total purchases by a pharmacy and the prescriptions being filled at that pharmacy. H.D. Smith can analyze the data to identify prescribing patterns that raise possible red flags regarding the pharmacy. By way of example, in February 2008, H.D. Smith requested, obtained, and evaluated dispensing and prescribing data from Hurley Drug Company ("Hurley Drug"), Tug

---

[1157] U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee).
[1158] *Id.*
[1159] U.S. Census Bureau, American FactFinder, *Williamson city, West Virginia*, https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml.
[1160] U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee).
[1161] *Id.*
[1162] *See* Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).